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# The Birmingham Bone Anchored Hearing Aid Programme Some Audiological and Quality of Life outcomes

By Sunil Dutt





**THE BIRMINGHAM BONE ANCHORED HEARING AID PROGRAMME**  
**Some Audiological and Quality of Life Outcomes**

Sunil N. Dutt



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# **THE BIRMINGHAM BONE ANCHORED HEARING AID PROGRAMME**

## **Some Audiological and Quality of Life Outcomes**

Een wetenschappelijke proeve  
op het gebied van  
de Medische Wetenschappen

### **PROEFSCHRIFT**

Ter verkrijging van de graad van doctor  
aan de Katholieke Universiteit Nijmegen,  
volgens besluit van het College van Decanen  
in het openbaar te verdedigen  
op dinsdag 28 mei 2002  
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door

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# General Introduction





## Introduction

The bone anchored hearing aid (BAHA) is now a well-established form of hearing rehabilitation in the United Kingdom. After a decade of experience (1988 to date) with osseointegration, the Birmingham BAHA team perceived the need for analysis of patient satisfaction, quality of life, wear and tear concerns and service related issues. Several questionnaire studies were undertaken to address these issues specifically. This thesis describes the results of the above questionnaire studies and our experience with the bilateral implantation of BAHA.

Before embarking on the role of questionnaire studies in evidence based medicine (EBM) terms, specifically in relation to BAHA, it is important to understand some basic concepts in the evolution of bone-conduction hearing habilitation.

## Bone conduction physiology

Understanding the mechanisms of bone conduction has developed over the last century and several ingenious methods of applying the same clinically have been devised.<sup>1,2</sup> The phenomenon of bone conduction, both physically and physiologically is of vital importance in both diagnosis of a hearing loss and in the development of hearing aids. Understanding hearing by bone conduction may be difficult as it involves sound transmission by wave motion in a complex geometrical structure of layered bone, covered with soft tissues and cartilage, and finally received by the highly delicate and complex cochlea.<sup>1</sup> Several theories of bone conduction have been put forward and these essentially allude to the meatal osseotympanic mode, ossicular inertial mode and the compressional modes of bone conduction.<sup>2,3</sup> High quality measurements of bone conduction are possible today with the use of computers, frequency analysers and miniature accelerometers. Although, there is linear transmission for normal sound levels in the skull, bone conducted sound can be severely affected by structural characteristics such as the anti-resonances of the skull. These anti-resonances cause transcranial attenuation of up to 40 dB resulting in a perceived sound localisation and lateralisation.<sup>4</sup>

From Cappivacci in the 16<sup>th</sup> century, Helmholtz and von Békésy in the 19<sup>th</sup> and 20<sup>th</sup> centuries, to the more recent work from Chalmers University, Gothenburg, our understanding of bone conduction physiology and pathology has seen phenomenal changes.<sup>4,5,6,7</sup>

## Hearing rehabilitation with conventional hearing aids: air and bone conduction

Ear trumpets and speaking tubes were in vogue in the 19<sup>th</sup> century. For centuries, cupping one's hand behind the ear was a learned behaviour that was used to circumvent the problem

of presbycusis. Inventions such as the telephone, the carbon microphone and vacuum tubes made the first electric hearing aids possible in the early 1920s.<sup>4</sup> In the 1960s improvements in transistor technology made behind-the-ear (BTE) aids a reality. Since then, conventional air conduction aids have seen a slow evolution to present day in-the-ear (ITE) and in-the-canal (ITC) digital hearing aids.

On the other hand, bone conduction aids technology did not receive as much attention simply because the patient group and hence the market for the same was limited. It is interesting to note that before electrical amplifiers and vibrators were available, vibrations from transmitted from the person talking to the hearing-impaired person listening by way of a rod!<sup>4</sup> Towards the end of the 19<sup>th</sup> century, pocket hearing aids with the bone receiver on a head band and bone conduction receiver incorporated into eyeglass temples were developed. No major developments occurred in the 20<sup>th</sup> century with bone conduction aids until the advent of the Bone Anchored Hearing Aid with its percutaneous implant in the 1980s. A few years later, a transcutaneous bone transducer (the Audiant Bone Conductor<sup>TM</sup>) was introduced by the Xomed Company that was discontinued due to lack of performance by its design principle.

### **The evolution of Osseointegration**

In the 1960s, Professor Per-Ingvar Branemark (University of Gothenburg, Sweden) found means and methods for establishing a direct bone contact and long term bonding between titanium implants and the human bone (Figure 1), a phenomenon aptly termed 'Osseointegration'.<sup>8,9</sup> The famous story of the 'rabbit ear chamber' used to study red blood cells in the bone marrow of the legs of rats and the accidental discovery of unbreakable bonding between the bone and the chamber metal (titanium) when Branemark wanted to retrieve the chambers, is well known. In Gothenburg, the titanium screws were first tested on dental implants and it became clear that if the screws were left unloaded for about 3 to 6 months, long term bonding with close apposition and anchorage between the titanium and bone surfaces was possible (Figure 2). Amid a lot of criticism in the 60s and 70s, the osseointegrated titanium implant made its mark first with dental prostheses with other areas of the body soon to follow, viz., craniofacial prostheses, bone anchored hearing prostheses and limb replacement prostheses.<sup>4</sup>

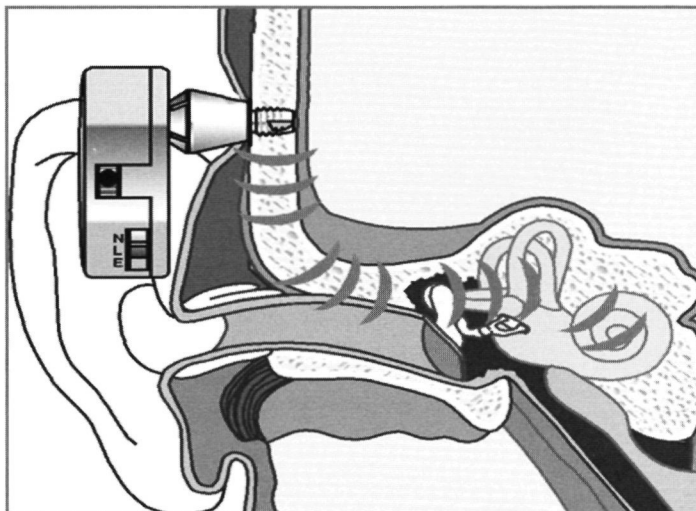


Figure 1. Direct Bone Conduction

### The Bone Anchored Hearing Aid (BAHA)

The concept of direct bone conduction with hearing aids, using the principle of osseointegration, was introduced by Tjellstrom *et al* and is achieved by using a skin penetrating coupling from a titanium implant in the mastoid bone to an impedance-matched transducer that the patients can apply and remove at will.<sup>3,10</sup> The titanium oxide surface is highly biocompatible and integrates with the osteocytes to form a stable interface that can withstand large stresses without displacement (Figure 2) and this osseointegration phenomenon takes about 6 weeks to 3 months to be complete. Direct bone conduction is achieved by the absence of interposing soft tissues and this gives better sound quality, requires less energy and offers much greater comfort.<sup>4</sup>

The BAHA is a percutaneous bone conduction hearing device secured to the skull by the process of osseointegration using a titanium fixture. The device rehabilitates those with a conductive type or a mixed type of hearing loss. Those that are not able to wear a conventional hearing aid are the primary beneficiaries. Long term outcome analyses from several pioneering centres have shown good stability of the device, audiological benefit, reduction of otorrhoea, increased comfort, patient satisfaction and improved quality of life.<sup>11,12</sup>

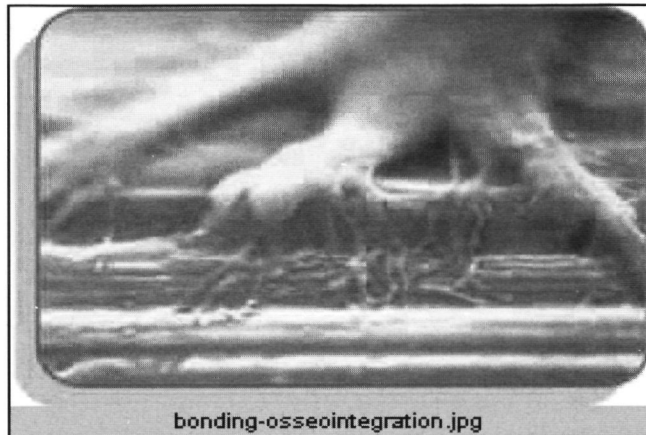


Figure 2. Osseointegration

The device reduces the risks of conventional hearing restoration surgery, is predictable and is suitable for paediatric use.<sup>13</sup>

### **The Gothenburg experience**

There is no contest to the facts that Gothenburg is the birthplace of Osseointegration and Prof Branemark, the 'Father of Osseointegration'. As mentioned above, the success of skin penetrating titanium implants resulted in the development of the bone anchored hearing aid (BAHA - Figure 3) under the direction of Anders Tjellstrom (Department of Otolaryngology, Sahlgren's Hospital, Gothenburg, Sweden) and Bo Hakansson (Department of Applied Electronics, Chalmers University of Technology, Gothenburg, Sweden).<sup>3,14</sup> The Branemark system was fully incorporated into the National Insurance System in Sweden by 1976 and in 1987, the first training courses on BAHA were started. Understandably, pioneering research in the field came from here.<sup>14-23</sup> The principles of osseointegration, the surgical considerations, evaluation of complications (including Holgers classification of wound problems at the assembly site) and the short and long term follow-up results have all been published from Gothenburg.<sup>10,11,14-25</sup> The technology has since been commercialised by the company Nobel Biocare (erstwhile Nobel Pharma) who are presently with Entific Medical Systems that has its Head Office in Gothenburg, Sweden and has regional offices all over the world.



Figure 3. The BAHA fixture, abutment and the hearing device

The phenomenon of bone conduction is being further studied at Sahlgrenska and Chalmers and further basic research is being undertaken. For example, the linearity of bone conducted sounds, the sensitivities and anti-resonances and the loudness of bone conducted sounds have been evaluated.<sup>4,7,26-28</sup> The value of a miniaturised artificial mastoid using a skull simulator in experiments has been studied.<sup>29</sup> The feasibility of BAHA for sensorineural impairment has been studied.<sup>30</sup> The new concept of mastoid cavity-implantable bone conduction hearing aid is being thoroughly evaluated, working towards a totally implantable bone conduction hearing device at the Department of Signals and Systems, Chalmers University (Hakansson and Stenfelt, Personal communication, 2001).

### The Nijmegen experience

The first percutaneous titanium implant was applied by Professor Cor Cremers of the ORL Department, University of Nijmegen in 1988. The percutaneous BAHA was compared to the transcutaneous Xomed device (twinned with the Academic Medical Centre, Amsterdam) and the twin project reports have been published.<sup>31</sup> With gratifying initial results adhering to the Recommendations from the Dutch Health Committee,<sup>12</sup> the Nijmegen group under the leadership of Prof Cremers has produced two Ph. D dissertations on the clinical and audiological aspects of BAHA.<sup>2,12</sup>

The technique of one-stage implantation of the BAHA including the use of a vertical incision for implant, the influence of skin and soft-tissue thickness on bone conduction thresholds and

multicentric clinical and audiological results with the original HC200 and HC220 BAHA models were included in the first thesis by EAM Mylanus in 1994.<sup>2 32-37</sup>

The group has furthered its areas of research on BAHA both surgically and audiological and has pioneered clinical trials with the BAHA including widening indications such as bilateral application. The second such series of research work was produced by CTM van der Pouw in 1998 as another Ph D thesis.<sup>12</sup> This includes amongst others, histological findings with removed titanium implants from the temporal bone, intra-individual comparisons of the BAHA with their previous air-conduction aids and the unit's experience with the BAHA Cordell and the bilateral BAHA application.<sup>38 45</sup> Since the BAHA showed to have better results compared to the conventional hearing aids in case the airborne gap was over 30 dB and since bilateral hearing proved to be there at a central level with bilateral BAHA application the Nijmegen team pioneered again by the application of the BAHA for a maximal unilateral conductive hearing loss in the affected ear having a non-affected normal hearing ear at the other side.<sup>46-47</sup> The unit is also involved in a multicentric of BAHA for single-sided deafness, both conductive and sensorineural hearing impairments, independently (Cremers CWRJ, Personal communication, 2001). A brief review of audiometric data for sensorineural hearing loss,<sup>48</sup> the audiological evaluation of bilateral BAHA application including sound localisation strategies,<sup>49</sup> and a brief overview of the state of the art with BAHA technology are the Nijmegen group's recent research publications.<sup>50</sup>

### **The Birmingham BAHA programme (1988 to date)**

The Birmingham Osseointegration Programme, UK was started in 1988 under the leadership of Mr David Proops, consultant otologist and paediatric otolaryngologist, Queen Elizabeth Hospital and Children's Hospital, Birmingham University. The team liaised with the local maxillo-facial unit who had some experience with the bone anchored intra-oral implants. Initial help and expertise was also received from Prof Tjellstrom's team from Gothenburg. Since the inception of the programme to date (i.e., time of questionnaire, Spring-Summer 2000), more than 500 patients including adults and children have received an osseointegrated implant. These include more than 350 patients with the BAHA. 15 patients have also received bilateral BAHA implants and the results are encouraging.

### *BAHA and FAITEC programme - the multidisciplinary approach*

Osseointegration is now firmly established in the surgical armamentarium of otologists. It has two major roles at the moment, firstly, for the fixation of bone anchored hearing aids and secondly, for the provision of bone anchored auricular prostheses and/or BAHAs in the

management of congenital ear abnormalities. The acronym FAITEC refers to the specialist multi-disciplinary clinics that are conducted every month and stands for Facial and Audiological Implantation Technology. This service as mentioned is best delivered by a well-founded multi-disciplinary team that would also be responsible for long term maintenance and after-care. On our programme, the team presently includes

- 1 Consultant Otologists (2 for the adult programme and 1 for the paediatric service)
- 2 1 Consultant Audiological Scientist
- 3 2 Audiological Scientists (one in each service, adult and paediatric)
- 4 2 Chief Audiologists (one in each service)
- 5 2 Hearing Therapists (one in each service)
- 6 2 Speech and language therapists (one in each service)
- 7 1 Advanced Nurse Practitioners (paediatric service)
- 8 2 Senior Registered Staff Nurses (BAHA nurses - adult programme)
- 9 1 Senior Maxillofacial Prosthetist and Laboratory Manager
- 10 2 Senior Anaplastologists
- 11 1 Geneticist
- 12 2 Senior Specialist Registrars and 2 Senior House Officers in Otolaryngology (one for each service)

We discuss hereunder the indications, assessment, surgical technique, outcome analysis and future directions with the Birmingham Programme, in particular

### *Indications*

The greatest beneficiaries are the legion of individuals who suffer from bilateral conductive or mixed hearing impairment secondary to chronic suppurative otitis media and who cannot be satisfactorily aided with conventional aids. The other groups include those with congenital deafness and aural atresias and a small number of cases with otosclerosis. Those that require auricular prosthesis should be referred to tertiary centres with multidisciplinary teams with well-established prosthetic and craniofacial links. Otosclerosis is a condition, which, in addition to stapedectomy may be managed by conventional hearing aids. However, there is a small group of patients who, by virtue of their age, occupation or personal choice do not wish to or cannot be advised to undergo stapedectomy and may not wish to or cannot use conventional aids. Such patients may be offered a BAHA as a third option <sup>51</sup>

The clinical indications may be summarised as follows

These are a group of patients who cannot wear conventional hearing aids



- 1 Those with congenital ear abnormalities who cannot be fitted with conventional air conduction aids
- 2 Those with a conductive or mixed hearing loss who are unable to wear conventional aids because of discharge, irritation or feedback (chronic suppurative otitis media and chronically draining mastoid cavities)
- 3 Those with otosclerosis who cannot or will not wear conventional aids and who will not contemplate stapedectomy
- 4 Those with unilateral conductive or mixed loss when the second ear is profoundly deaf and correctional otosurgery carries too great a risk
- 5 Age is no bar and children with congenital hearing impairment can be successfully habilitated as young as two years <sup>13</sup>

### *Investigations and Management*

The primary investigation is audiological. Questionnaires can be helpful to exemplify the problems followed by pure tone audiometry, aided and unaided thresholds and speech audiometry. The recommendations are for bone conduction thresholds no worse than 45 dB for the ear level device (BAHA Classic and recently Compact) and 60 dB for the body worn one (BAHA Cordelle). The decision as to the suitability and advisability of the BAHA for a particular patient is made in the multidisciplinary clinic and a treatment plan formulated to include long-term management and maintenance.

On the Birmingham bilateral BAHA programme, adult patients with symmetrical hearing loss (four tone average thresholds within 15 dB of each other) are considered for bilateral BAHAs. Patient's professional needs and motivation are important inclusion criteria. It is likely to be extended to paediatric patients in the near future. A proposal for a prospective multicentric randomised controlled trial (RCT) to evaluate the benefits of bilateral BAHAs is being considered that may include co-operation with Nijmegen, Gothenburg and Manchester.

### *Surgical techniques*

The surgical technique has seen several modifications from the traditional postaural skin graft technique to the more recent local split skin graft method <sup>52</sup>. Most techniques address the importance of soft tissue reduction: the original Tjellstrom method with a free postaural skin graft, the Browning method with transpositional flaps, the Cremers method with a straight line incision, the Proops method with a thinned pedicle flap and the Rothera method with a free local skin graft <sup>52 54</sup>. A combination of the Proops and Rothera methods are used in implanting BAHAs in Birmingham.

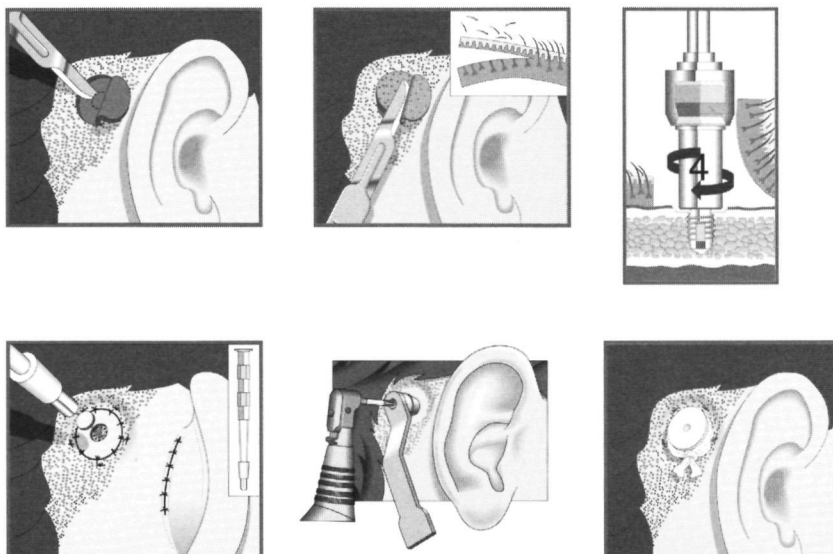


Figure 4. Surgical Procedure

Surgery must be meticulous (Figure 4), the site chosen should be planned using a template and the side decided with the patient depending on their requirements such as handedness and car driving.

In the vast majority of adults the surgery is performed under local anaesthesia with some preferring light sedation; children however will require general anaesthesia with a two-staged procedure but it always can be performed as a day case.

The preferred site invariably falls within a hair-bearing region. 6 mls of local anaesthetic is infiltrated after shaving the area. An inferiorly based split thickness skin graft is raised using a Silver's dermatome and the soft tissues down to the periosteum excised. The periosteum is minimally opened using a cruciate incision and then the special equipment needed to insert the titanium 'fixtures' used. The essence of this part is the production of a threaded hole at 90 degrees to the bone surface into which the titanium fixture (3 mm or 4 mm) is inserted with absolutely minimal trauma to the living osteocytes. This would then constitute the end of the first stage in a child but in an adult the 'abutment' which is the attachment for the aid is now fitted and the skin closed with only the abutment protruding. The wound is dressed using ribbon gauze soaked in steroid antibiotic cream and 3 months later when osseointegration has occurred the aid is ready to be fitted (Figure 5).

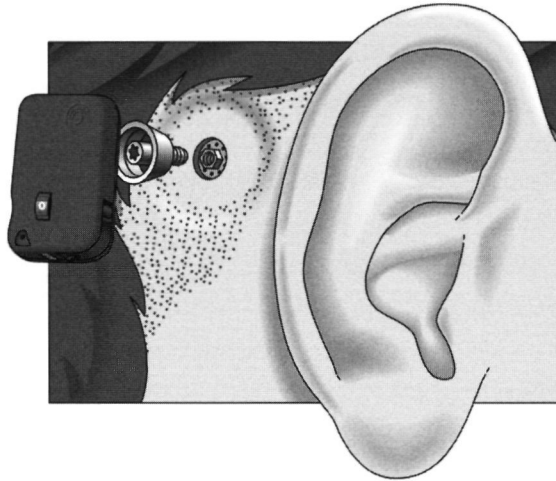


Figure 5. The BAHA in situ

The Company (Entific Medical Systems, Head Office, Gothenburg, Sweden) provides a complete package and kit of instruments including stainless steel sets, titanium sets and mounting systems and the drill systems with special functions. BAHA workshops and master-classes are organised throughout the year in various centres of the world including Birmingham.

#### *BAHA Nursing*

2 BAHA nurses (adult), one advanced nurse practitioner (paediatric) are responsible for the after-care and follow up of the patients' initially until fitting of the BAHA. This includes regular dressings and inspection and care of the skin graft/flap and cauterisation of small granulations, removal of crusts and topical terramycin-hydrocortisone cream application. They are also responsible later, i.e., after aid-fitting, for any wound or flap related issues on a 'when required' basis. All three on the nursing team are actively involved in the teaching aspects of the BAHA programme.

#### *Paediatric experience*

The first child to be implanted with a BAHA on the Birmingham programme was in 1990. Since then 109 children have been implanted with a BAHA (as of April 2000) of which, 8 children had worn the BAHA for less than 6 months. The youngest child implanted is 2 years of age and the general consensus is that if the audiological and the psychosocial criteria are

met, the sooner a child is implanted the better the outcome. The surgical technique in children is a two-stage procedure as the skull thickness in younger children may not be satisfactory for a one stage stable integration. Experience with the use of bone-chips and pate and Gortex<sup>®</sup> membranes in a small series of thin-skulled individuals has been gratifying. In such children, the second stage is performed after four months to allow for adequate osseointegration.

### *Outcome Measures and Evidence of Benefit*

Evidence of benefit can be obtained from audiological testing and questionnaire feedback. Audiological evaluation includes unaided and aided thresholds, speech recognition in quiet, soundfield assessments with AB word lists, speech in noise evaluation using BKB sentences at signal to noise ratios (SNR) of -10, 0 and +10, Plomp multitalker test and sound localisation tests.

With hearing rehabilitation, questionnaire studies that are useful include quality of life questionnaires such as the Glasgow Benefit Inventory (GBI), comparative questionnaires such as the Nijmegen group questionnaire and the Glasgow Hearing Aid Benefit Profile (GHABP) and service related questionnaires such as the Entific Medical Systems questionnaire (Chapters 2,3,4 and 5).

On the Birmingham programme, the wearing time for 90 % of the BAHA users was all the waking day and the audiological results showed improvement with their BAHA as compared to their previous aid in both the adult and the paediatric programmes.

Complications are almost all due to soft tissue problems around the abutment due either to inadequate thinning or poor hygiene. On the Birmingham programme, loss of the titanium fixture occurred in 10% of patients overall but this was more common in children and early on in the series. A standardised scoring system (Holgers classification) is available for the uniform reporting of wound related problems including fixture failures and losses from different centres.<sup>25</sup>

In Birmingham, the non-wearer rate has been less than 2% and the majority is because the patient is experiencing deteriorating hearing making the aid unsuitable. Initial experience (1988-1995) with the BAHA from Birmingham has been published as a supplement of the Journal of Laryngology and Otology in 1996. This includes the comparison of different surgical techniques, the referrals, selection and rehabilitation protocols for both adults and children, the role of the BAHA in otosclerosis, the benefits of BAHA in patients with chronically draining ears and the role of the speech and language therapist in bone-anchored hearing and aural rehabilitation.<sup>13 51 52 55-58</sup>

### *Recent advances and the future - the new era of Implantation Otology*

A big step forward with this technology is the recent demonstration of benefit with bilateral implantation. The Nijmegen group has demonstrated that bilateral BAHA implantation produces binaural hearing<sup>49</sup>. This provides speech intelligibility, sound localisation and stereophonic perception. The experience in Birmingham has been similar and is discussed in this dissertation.

As with most technologies, miniaturisation is an important advance with the BAHA. The BAHA compact (Figure 3) is smaller and with the new 'snap coupling' that replaces the previous 'bayonet coupling' with the abutment, BAHA users are pleased as regards the ease of use. Many of the patients attending the BAHA clinics have had their abutments changed to the snap-coupler. Incorporating digital technology will be the next important landmark and this would also enable remote controlled features.

The surgical technique has seen some dramatic changes. We have now moved to a single-stage technique from a previously described two-stage technique for adult BAHA implantation. The bothersome step of 'hex-locking' the abutment no longer exists. The Company has produced a new dermatome that is being evaluated for its precision, accuracy and ease of use. Also on trial is a new 'self-tapping single mount' (fixture-abutment assembly) system that appears to be extremely user-friendly.

### **Entific Medical Systems: FDA Approvals and World-wide Distribution**

Entific Medical Systems (and Nobel Biocare) is the sole manufacturer and distributor of the BAHA and other facial and intraoral implants throughout the world. The Company has its head office in Gothenburg, Sweden and has subsidiary offices all over the world including Holland, UK, Belgium, Germany, France, USA and Canada. FDA approvals for the initial product for unilateral application were obtained in 1996 using the Gothenburg experience. Approval for the paediatric application of the BAHA came in 1999 and was brought by the limited experience from Birmingham (21 cases)<sup>13</sup>. More recently, i.e. 2001, the approval for bilateral application in patients with quite symmetrical sensorineural hearing loss component has been achieved by the scientific data produced by the Nijmegen group<sup>49</sup>.

### **Composition of this dissertation: The Evidence Base for BAHA**

In this day and age of evidence based medicine, studies addressing every aetiological or epidemiological factor, diagnostic test and therapeutic or management interventions have undergo the scrutiny and critical appraisal and reappraisal of peer review. These are then classified, based on the strengths of the study design and the robustness of an outcome

analysis including statistics into 'Level's of Evidence'<sup>59</sup> For example, with studies addressing the management protocols and interventions, Level 1 evidence is one obtained by a meta-analysis of randomised controlled trials (RCT) It is possible that many conditions and hence their management plans may not be ethically and morally viable for planning of an RCT and hence other levels of evidence or study designs may be invoked When a longitudinal study has not been undertaken, a cross-sectional outcome analysis may be considered and such an analysis includes questionnaire surveys

### ***Outcome domains***

The World Health Organisation has categorised the impact of a disease state as one of the following<sup>60</sup>

- 1 *Mortality*
- 2 *Functional morbidity impairment of function* This refers to limitation of function of a body part For e g , in the context of this thesis, hearing impairment
- 3 *Disability* refers to restriction in daily activity directly as a result of the impairment
- 4 *Handicap* Impact on the individual's social activity directly as a result of the disability
- 5 *Distress* This relates to the psychological reaction to a disease state and its impact

The above domain definitions have been applied in studying our patient population with specific reference to the impact of BAHA as an intervention

### ***Patient Satisfaction and Quality of life issues (Chapters 2,3,4 and 5)***

After more than a decade of experience with Bone Anchored Hearing Aid Implantation (1988 to date), the Birmingham group deemed it necessary to conduct a cross-sectional survey amongst the patient population to evaluate patient satisfaction and quality of life with the BAHA This was undertaken on a study 'cohort' of 312 patient that included 211 adults and 101 children that had used their BAHA for a minimum period of 6 months (from the fitting stage) Table 1 of Chapter 2 details the distribution of the cohort Chapters 2,3 and 4 refer to the same cohorts that were studied using postal questionnaires Chapter 5 provides a detailed evaluation of the specific outcome domains discussed above on a small cohort of patients that had an interview-based questionnaire administered

### ***Questionnaire studies***

The systematic collection of quality of life (QOL) data using validated instruments is extremely important to establish a database of information about the effects of treatment, to

enable better decision making by the doctor and the patient and to assist in the evaluation of efficacy of treatment in clinical trials. Questionnaires may be classified into

- 1 *Open and closed questionnaires* In a closed question the responder is given a multiple choice of responses to choose from. This may be as simple rank order (mild, moderate or severe) or a rank-order scale such as the Likert scoring scale (Glasgow Benefit Inventory)<sup>61</sup> or a Visual Analogue Scale (VAS, as has been used in Chapters 2 and 6)
- 2 *Reliable or unreliable questionnaires* Reliability refers to whether the instrument will produce the same result when administered repeatedly to an individual
- 3 *Validated or non-validated questionnaires* Validity is concerned with whether the instrument is actually measuring what it purports to be measuring. For example, the Glasgow Benefit Inventory (GBI) used in chapters 2 and 6 and the Glasgow Hearing Aid Benefit and Difference Profiles (GHABP and GHADP)<sup>62</sup> used in chapter 5 are examples of validated and reliable questionnaires
- 4 *Postal or interview based questionnaires* A cross-sectional analysis of responses may be administered by a postal questionnaire, if the questions and responses are simple and easily understandable, e.g., the GBI, the Nijmegen group questionnaire and the Entific Medical Systems questionnaire. However, the divisions and stems of certain complex questionnaires are only suitable for interview based responses as was observed with the GHABP and GHADP discussed in chapter 5

### ***The difficulties in administering questionnaires***

The biggest difficulty we faced was with the postal questionnaires. It was apparent that many of the adolescents in the paediatric group (at the time of implantation, i.e., age less than 16 years) had moved on to the adult programme for follow-up and after care. The consensus however was to administer the questionnaires with reference to age at implantation.

The second issue was the fact all the questionnaires used in the study have been validated for adult population and not really for children. Also, some of the children on the paediatric programme are very young to comprehend some of the questions asked even with the help of their parents. Of the 101 children and adolescents that received the questionnaires, there were only 40 responders and the rest (61) did not respond. With the above two issues in mind, any attempts at cleaving the responses into paediatric and adult groups proved difficult and seemed irrelevant. In general, the responses of both the adult and paediatric groups were comparable with these three questionnaires (data not in figures and tables). These factors that were identified during the study have helped us generate separate satisfaction



and QOL questionnaires for children under 12 years of age and for adolescents between 12 and 16 years of age. Further studies are being undertaken by the Paediatric BAHA team. The issue of the model of BAHA used was also a difficult confounding variable. Many of the patients on both the programmes had used various models for variable periods of time. The GHABP and the GHADP were clearly questionnaires that warranted an interview-based technique and a longitudinal prospective study is in progress with the adult programme. The responses of the first cohort of 84 patients interviewed in follow-up clinics are presented in chapter 5.

### ***Binaural hearing and bilateral HA fitting (Chapters 6, 7 and 8)***

Encouraged by the data published by the Nijmegen group with bilateral BAHA application (made available by the publication of van der Pouw's thesis in 1998), our programme was approached by some of the patients for a second side BAHA. Since 1995, 15 patients have been implanted with bilateral BAHAs and the subjective and objective evaluation outcomes are presented in chapters 6 and 7.

Bilateral conventional hearing aid fitting is a service that is not widely practised in the United Kingdom. The Knowledge, Attitudes and the Practice of bilateral hearing aid fitting amongst ENT surgeons in the country were evaluated in early 2000 via a postal questionnaire. This was a questionnaire that was derived after piloting with a group of thirty local consultants and is by no means a validated and reliable questionnaire. However, the instrument was useful in generating data that would help address the problems and dilemmas faced by NHS (National Health Service) consultants and audiologists throughout the country.

### ***Reduction of complications (Chapter 9)***

3% of the patients in both the programmes were non-users at the time of the survey (Spring-Summer 2000). Some of the issues related to temporary non-use were wound infection and soft-tissue prolapse. The problem of inadequate soft-tissue reduction has been addressed by the short surgical technique that describes a radial-four flap method to achieve the desired degree of excision of soft tissue without compromising flap vascularity.

### **Acknowledgement**

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# **PART I**

## **Patient satisfaction and quality of life issues**



# Chapter 2

## **The Glasgow Benefit Inventory in the evaluation of patient satisfaction with the bone anchored hearing aid - Quality of life issues**

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## Abstract

The Birmingham osseointegration programme began in 1988 and during the following ten years there were a total of 351 Bone Anchored Hearing Aid (BAHA) implantees. In the Summer of 2000, a postal questionnaire study was undertaken to establish the impact of the bone-anchored hearing aid on all aspects of patients' lives.

We used the Glasgow Benefit Inventory (GBI), which is a subjective patient orientated post-interventional questionnaire especially developed to evaluate any otorhinolaryngological surgery and therapy. It is maximally sensitive to any change in health status brought about by a specific event. In this case the provision of a BAHA.

A total of 312 bone anchored hearing aid patients, who had used their aids for a minimum period of 6 months, were sent GBI questionnaires. 227 questionnaires were returned and utilised in the study. The results revealed that the use of a bone-anchored hearing aid significantly enhanced general well being (patient benefit), improved the patient's state of health (quality of life) and finally was considered a success by patients and their families.

## Introduction

The Bone Anchored Hearing Aid has provided an alternative to conventional air and bone conduction hearing aids particularly in situations of chronic middle ear infections, congenital aural atresia and chronic otitis externa.<sup>1</sup>

Since 1977 osseointegrated implants have been shown to provide excellent retention for the bone-anchored hearing aid. During the past twenty-four years these alternative hearing aids have become increasingly popular. The hearing aid component has recently been manufactured as a more compact device, thus improving its aesthetic appearance.

In a minor surgical procedure performed under local anaesthesia for the majority of patients, a titanium fixture is implanted into the temporal bone. The periosteum of this implant site is removed and the surrounding subcutaneous tissue trimmed. A percutaneous abutment is then attached to the fixture. Three months later, the bone-anchored hearing aid is connected to the abutment. This simple implant technique has made the provision of these bone-anchored hearing aids less traumatic for the patient and overall, more cost effective.

The Birmingham BAHA programme has implanted both paediatric and adult patients. An evaluation of patient satisfaction and quality of life after BAHA implantation was undertaken.

## **Patients and Methods**

The Glasgow Benefit Inventory (GBI) questionnaire along with a pre-paid envelope was sent to each patient, irrespective of their age, for completion in their own homes. This instrument was described by Robinson *et al* in 1996<sup>2</sup> consisting of 18 questions (Appendix 1). The questionnaire was designed to be completed either at interview or by the patient in their own home.

These 18 questions were based on a five point Likert scale. Half of the questions ranged from a large deterioration in health status to a large improvement in health status. The design of the other half of the questions was reversed. This was to control response bias.

The original 18 question GBI was first scored into a total score. It was then scored into the three subscales below -

- a Twelve questions relating to general factors
- b Three questions relating to social support issues
- c Three questions concerning physical health

Two additions were made to our questionnaire. Four questions relating to the success of the BAHA (Appendix 2) and a 10 cm linear analogue scale reflecting state of health before and after BAHA (Appendix 3). Neither of these modifications was described in the original GBI strategy.

The total score for each patient was calculated and then averaged to give equal weight to each question. 3 (no change) was subtracted from the total and the result multiplied by 50 to produce a benefit score. All these scores ranged from -100 to +100.

The same analysis was used for each of the subscales.

The Wilcoxon signed ranks test was used to evaluate the linear analogue scale since it took into account not only the signs of the differences but also their magnitude.

This study was a retrospective postal questionnaire with a four months' waiting time for responses from the 312 patients. Subjects who had worn their BAHA for more than 6 months were included in the study. This was to avoid initial 'enthusiasm bias', allow a gradual learning process with the BAHA and to obviate initial difficulties with fitting and maintenance. A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

## **Results**

In 1988 the Birmingham Bone Anchored Hearing Aid programme was started and during the following decade a total of 351 patients were implanted.

Table 1. Distribution of response rates

Total number of implantees	351	(242 adults and 109 children)
Total included in the study	312	(6 months or more of BAHA use)
Number excluded	39	(less than 6 months of BAHA use) (31 adults and 8 children)
Total respondents	227	(72% response rate)
Total non-respondents	85	
Adults (211)	187	respondents (89%)
	24	non-respondents (11%)
Children (101)	40	respondents (40%)
(under 16 years)	61	non-respondents (60%)

This study group consisted of 242 adults and 109 paediatric patients. The adult age range was 17 to 67 years (median age 45 years) and the paediatric range was 2 to 16 years (median age 9 years). 187 patients were male and 164 were female.

39 bone anchored hearing aid patients had worn their hearing aid for less than six months and so they were excluded from the study. 312 GBI questionnaires were issued and 227 were completed and returned (72%). Of the 85 non-respondents, 61 (72% of 85) were children. The patients that returned the questionnaire had used their BAHA for a period of 6 months to 11 years (mean 5.8 years). Table 1 illustrates the response rate of the study group.

This GBI questionnaire was initially shown to measure the change in health status (benefit) from various otolaryngological interventions.<sup>3-6</sup> In our study, the benefit of wearing a bone anchored hearing aid (quality of life), the success of wearing such a hearing aid and a measure of the health status both prior to and after wearing their bone anchored hearing aid was evaluated.

The GBI questionnaire comprised of eighteen questions each consisting of five-answer stems known as a five-point Likert scale ranging from a large change for the worse to a large change for the better (Table 2). In the original paper describing the GBI, the score from the Likert scale was then transposed onto a benefit scale ranging from +100 to -100. The same analysis was utilised for the data in this study.

Table 2. Example of questions used in the Glasgow Benefit Inventory Questionnaire

*How successful do you think your BAHA is?*

- |                                    |           |
|------------------------------------|-----------|
| <b>A</b> Great or moderate failure | (score 1) |
| <b>B</b> Partial failure           | (score 2) |
| <b>C</b> No change                 | (score 3) |
| <b>D</b> Partial success           | (score 4) |
| <b>E</b> Great or moderate success | (score 5) |

Table 3. Results of GBI questionnaire

Question	Median	Interquartile Range	No. of each answer				
			5	4	3	2	1
a. Effect on life	5	(4.0, 5.0)	131	51	40	3	2
b. Overall effect on life	5	(4.0, 5.0)	137	60	23	2	3
c. Optimism about future	4	(4.0, 5.0)	102	62	56	3	1
d. Embarrassment with BAHA	4	(3.0, 5.0)	108	64	42	6	3
e. Self confidence with BAHA	4	(4.0, 5.0)	101	70	47	5	1
f. Dealing with company	4	(4.0, 5.0)	95	85	38	4	2
g. Support from friends	3	(3.0, 4.0)	29	39	136	15	5
h. Visits to GP	3	(3.0, 4.0)	32	46	136	7	2
i. Confidence- Job opportunities	3	(3.0, 4.0)	44	62	96	11	7
j. Self consciousness	4	(3.0, 4.0)	52	75	72	15	10
k. People who care	3	(3.0, 3.0)	19	24	174	3	4
l. Frequency of illness	3	(3.0, 4.0)	23	54	140	3	4
m. Frequency of medication	3	(3.0, 3.0)	17	37	152	14	5
n. Self-opinion	4	(3.0, 5.0)	75	94	47	6	2
o. Family support	3	(3.0, 4.0)	24	44	147	9	1
p. Inconvenience	4	(4.0, 5.0)	84	88	38	11	2
q. Social activities	4	(3.0, 4.0)	30	86	95	12	2
r. Social situations	4	(3.0, 5.0)	63	65	77	14	6

In scoring the GBI, all responses to individual questions were averaged so that each question carried equal weight. The data was not distributed normally and so median values were calculated.

Table 3 shows the results of the questionnaire. Patient benefit was found to be significantly improved following implantation with a bone anchored hearing aid. In no situation did provision of a bone anchored hearing aid result in a deterioration of health.

When asked about the success of their bone anchored hearing aid, the overwhelming response was extremely positive (Table 4 and Figure 1). A remarkable 167 (74%) would encourage others with a similar condition to wear a bone anchored hearing aid.

Table 4. Success of BAHA

Question	Median	IQ Range	No. of each answer				
			5	4	3	2	1
a. Success of BAHA	5	(4.0, 5.0) <sup>1</sup>	170	45	3	3	4
b. Pleased/disappointed	5	(4.0, 5.0)	187	24	2	6	6
c. Family opinion	5	(4.0, 5.0)	159	48	9	4	5
d. BAHA recommendation	5	(4.0, 5.0)	168	43	7	3	3

*IQ Range - Inter-Quartile Range*

## Success Of BAHA

### Modification 1

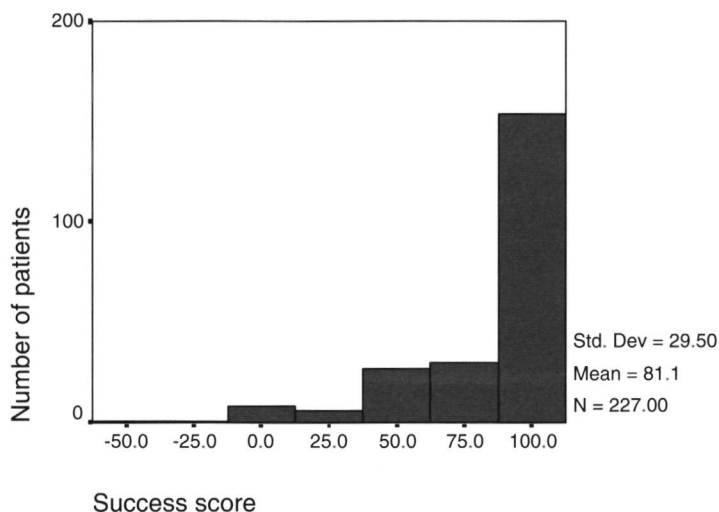


Figure 1.

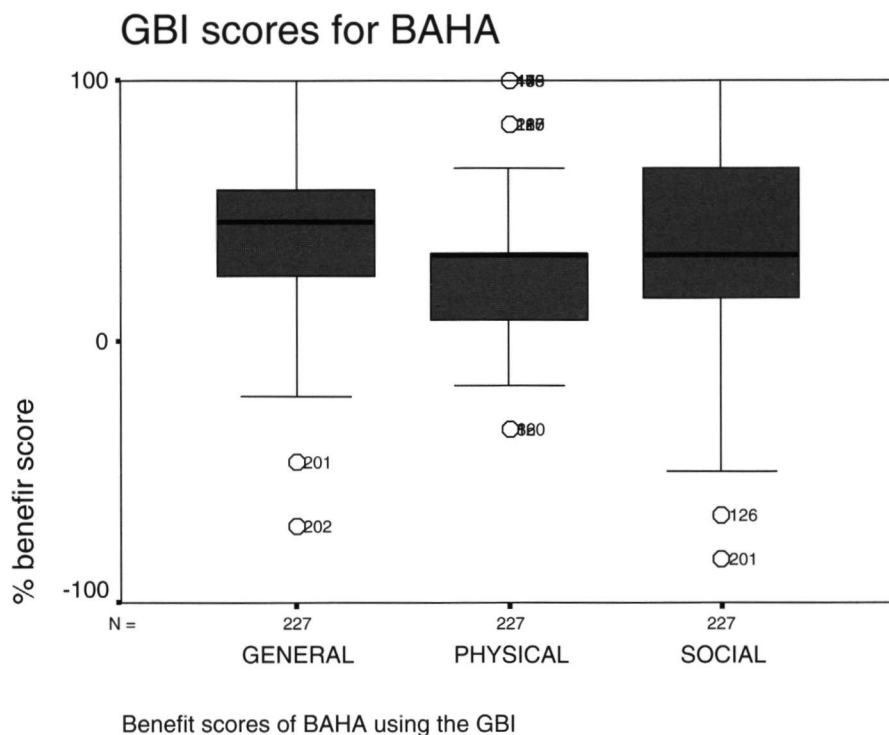


Figure 2. *Benefit scores of BAHA using the GBI.*(Questions a-l were about *general benefit*, m-o were about the *physical benefit* and finally p-r pertained to the *social benefit*)

Figure 2 represents the summary of the results of the 18 question GBI. It shows the results of each of the three individual subscales. The data is displayed as 'Box and Whisker' plots. In each group the median and 25<sup>th</sup> and 75<sup>th</sup> percentiles are displayed. In all three groups the results were very encouraging.

The ten centimetre linear analogue scale was included in the questionnaire to directly address the state of health both before and after obtaining a bone anchored hearing aid (Appendix 3). For analysis of this linear analogue scale the (non-parametric) Wilcoxon Signed Ranks Test was used. This showed that the improved state of health of the patients following the use of a bone anchored hearing aid to be highly significant (Table 5).

Table 5. Visual analogue scale regarding State of Health before and after BAHA

	State of health pre BAHA	State of health post BAHA	Difference
Median	56	85	15
Inter-quartile range	(45,76)	(72,91)	(0,30)

*Wilcoxon signed ranks test (  $p < 0.001$  )*

## Discussion

The Glasgow Benefit Inventory questionnaire is a patient orientated questionnaire designed initially to consist of eighteen post-intervention questions. It provides a measure of patient benefit (change in health status) from otorhinolaryngological procedures. It was first developed in 1996 by Robinson *et al.*<sup>2</sup> The GBI allows a comparison of benefit across different interventions.<sup>3-6</sup> It is designed to measure change in health status, where health status is defined as the general perception of well-being. This includes total psychological, social as well as physical well-being.<sup>7</sup>

In this study the modified GBI questionnaire consisted of 22 questions and a linear analogue scale. A response rate of 72% was achieved. This included both adult and paediatric patients (Table 1).

In response to the modification of the GBI (Appendix 2), these four additional questions regarded the success of the bone-anchored hearing aid. Patients recorded a maximum change for the better (Figure 1). The bone-anchored hearing aid was a success. There appeared to be no change with regards to the number of visits to the GP, support of family and friends and confidence with regards job opportunities. Interestingly, many patients reported annoyance at being asked such questions. They felt fully supported and cared for by their family and friends irrespective of the type of hearing aid worn. All remaining questions revealed the bone-anchored hearing aid to have a positive effect on their health status. This was supported by the very significant results of the linear analogue scale  $p < 0.001$  (Appendix 3 and Table 5).

This study did not compare different otolaryngological procedures; it was simply used to establish the effect of the bone-anchored hearing aid on patient health status. In the validation study by Robinson *et al* cochlear implantation was one of the interventions evaluated.<sup>2</sup> The GBI was found to be responsive to cochlear implantation. Its use to evaluate



hearing aid devices was recommended. Only one other study in the literature discusses the use of the GBI following the provision of the bone-anchored hearing aid<sup>6</sup>. Our study is on a large group of patients using the BAHA and the results were overwhelmingly supportive for the use of the bone-anchored hearing aid.

This study was a retrospective postal questionnaire. Some of the patients in the study had worn their bone-anchored hearing aid for ten years. Memories of problems prior to their bone-anchored hearing aid may have faded with time and this of course may be reflected in the results. The GBI is not very sensitive to changes in health status following provision of the bone-anchored hearing aid, it is designed as a benefit questionnaire. The addition of the linear analogue scale has provided details of the health status both before and after provision of the hearing aid.

An attempt to cleave data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. However, 72% of the non-respondents were children. Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e., BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in figures and tables). This data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the Company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

Finally, patient benefit was found to be improved by wearing the bone-anchored hearing aid and it significantly improved patient health. The study shows the bone-anchored hearing aid to be a success. Since the provision of such an aid involves a minor surgical procedure suitable with local anaesthesia, the authors suggest it should be considered more often for patients with chronic otorrhoea and otosclerosis.

## **Conclusions**

An overwhelming majority of the patients that included both adults and children reported a high degree of satisfaction with the bone anchored hearing aid. Improved self confidence, better job opportunities and better participation in social activities were some of the 'quality of life' issues that were highlighted. The Glasgow Benefit Inventory proved to be a valuable instrument in evaluating patient satisfaction and quality of life after BAHA implantation.

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## Appendix 1:

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### The Glasgow Benefit Inventory (GBI) Questionnaire

*This questionnaire asks how things have changed since you received your BAHA*

- a) Has getting a BAHA affected the things you do?
  - Option 1 Much worse
  - Option 2 A little or somewhat worse
  - Option 3 No change
  - Option 4 A little or somewhat better
  - Option 5 Much better
- b) Has getting a BAHA made your overall life better or worse?
  - Option 1 Much better
  - Option 2 A little or somewhat better
  - Option 3 No change
  - Option 4 A little or somewhat worse
  - Option 5 Much worse
- c) Since you received your BAHA, have you felt more or less optimistic about the future?
  - Option 1 Much more optimistic
  - Option 2 More optimistic
  - Option 3 No change
  - Option 4 Less optimistic
  - Option 5 Much less optimistic
- d) Since you received your BAHA, do you feel more or less embarrassed with a group of people?
  - Option 1 Much more embarrassed
  - Option 2 More embarrassed
  - Option 3 No change
  - Option 4 Less embarrassed
  - Option 5 Much less embarrassed
- e) Since you received your BAHA, do you have more or less self-confidence?
  - Option 1 Much more self-confidence
  - Option 2 More self-confidence
  - Option 3 No change
  - Option 4 Less self-confidence
  - Option 5 Much less self-confidence
- f) Since you received your BAHA, have you found it easier or harder to deal with company?
  - Option 1 Much easier
  - Option 2 Easier
  - Option 3 No change
  - Option 4 Harder
  - Option 5 Much harder
- g) With your BAHA, do you feel that you have more or less support from your friends?
  - Option 1 Much more support
  - Option 2 More support
  - Option 3 No change
  - Option 4 Less support
  - Option 5 Much less support

- 
- h) With your BAHA, have you been to your family doctor for any reason, more or less often?  
Option 1 Much more often  
Option 2 More often  
Option 3 No change  
Option 4 Less often  
Option 5 Much less often
- i) Since you received your BAHA, do you feel more or less confident about job opportunities?  
Option 1 Much more confident  
Option 2 More confident  
Option 3 No change  
Option 4 Less confident  
Option 5 Much less confident
- j) Since you received your BAHA, do you feel more or less self-conscious?  
Option 1 Much more self-conscious  
Option 2 More self-conscious  
Option 3 No change  
Option 4 Less self-conscious  
Option 5 Much less self-conscious
- k) Since you received your BAHA, are there more or fewer people who really care about you?  
Option 1 Many more people  
Option 2 More people  
Option 3 No change  
Option 4 Fewer people  
Option 5 Much fewer people
- l) Since you received your BAHA, do you catch colds or infections more or less often?  
Option 1 Much more often  
Option 2 More often  
Option 3 No change  
Option 4 Less often  
Option 5 Much less often
- m) Since you received your BAHA, have you had to take more or less medicine for any reason?  
Option 1 Much more medicine  
Option 2 More medicine  
Option 3 No change  
Option 4 Less medicine  
Option 5 Much less medicine
- n) Since you received your BAHA, do you feel better or worse about yourself?  
Option 1 Much better  
Option 2 Better  
Option 3 No change  
Option 4 Worse  
Option 5 Much worse
- o) Since your BAHA, do you feel that you have more or less support from your family?  
Option 1 Much more support  
Option 2 More support  
Option 3 No change  
Option 4 Less support  
Option 5 Much less support

- p) Since your BAHA, are you more or less inconvenienced by your hearing problem?
- Option 1 Much more inconvenienced
  - Option 2 More inconvenienced
  - Option 3 No change
  - Option 4 Less inconvenienced
  - Option 5 Much less inconvenienced
- q) Since your BAHA, have you been able to participate in more or fewer social activities?
- Option 1 Many more activities
  - Option 2 More activities
  - Option 3 No change
  - Option 4 Fewer activities
  - Option 5 Many fewer activities
- r) Since your BAHA, have you been more or less inclined to withdraw from social situations?
- Option 1 Much more inclined
  - Option 2 More inclined
  - Option 3 No change
  - Option 4 Less inclined
  - Option 5 Much less inclined

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**Appendix 2:**

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**Modifications: Subjective opinions regarding success of BAHA**

- a) How successful do you think your BAHA is?
    - Option 1 Great or moderate failure/1
    - Option 2 Partial failure/2
    - Option 3 No change/3
    - Option 4 Partial success/4
    - Option 5 Great or moderate success/5
  
  - b) Do you feel pleased or disappointed about getting a BAHA?
    - Option 1 Greatly or moderately pleased/5
    - Option 2 A little or somewhat pleased/4
    - Option 3 No change/3
    - Option 4 A little or somewhat disappointed/2
    - Option 5 Greatly or moderately disappointed/1
  
  - c) How successful do members of your family and close friends think your BAHA is?
    - Option 1 Great or moderate success/1
    - Option 2 Partial success/2
    - Option 3 No change/3
    - Option 4 Partial failure/2
    - Option 5 Great or moderate failure/1
  
  - d) If you knew that someone else in your family or a close friend had a similar condition to yours, would you encourage them to get a similar BAHA?
    - Option 1 Definitely not/1
    - Option 2 Probably not/2
    - Option 3 Can't decide/3
    - Option 4 Probably yes/4
    - Option 5 Definitely yes/5
-

### Appendix 3:

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#### **Modification : State of health before and after BAHA**

We would like you to indicate your state of health. To help you, we would like you to imagine a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Think about how your health affects:

- Your general well-being
- Your independence and ability to take care of yourself
- Your ability to take care of others
- How you feel about yourself
- Your ability to get around and communicate
- Your ability to socialise
- Your performance at work

#### **YOUR STATE OF HEALTH TODAY WITH YOUR BAHA**

We would like you to choose a point on the scale that indicates how good or bad you consider your state of health is today with your BAHA

Worst-----Best

#### **YOUR STATE OF HEALTH BEFORE YOU RECEIVED YOUR BAHA**

Worst-----Best

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# Chapter 3

## **An intra-individual comparison of the previous conventional hearing aid with the bone anchored hearing aid - The Nijmegen group questionnaire**

Ann-Louise McDermott, Sunil N Dutt, Andrew P Reid, David W Proops

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## Abstract

By Spring 2000, a total of 351 patients were implanted on the Birmingham Bone Anchored Hearing Aid (BAHA) programme. This group consisted of 242 adults and 109 children.

The aim of this retrospective questionnaire study was to directly assess patient satisfaction with their current bone-anchored hearing aid in comparison with their previous conventional air and/or bone conduction hearing aids.

The Nijmegen group questionnaire was sent by post to 312 patients who used their BAHA for 6 months or longer. The questionnaire used was first described by Mylanus *et al* (Nijmegen group) in 1998. The total response rate was 72% (227 of 312 patients). The bone-anchored hearing aid was found to be significantly superior to prior conventional hearing aids in all respects.

## Introduction

The percutaneous bone conduction hearing aid was first developed by Hakansson in 1985.<sup>1</sup> The Bone Anchored Hearing Aid (BAHA) connects directly to an osseointegrated titanium percutaneous implant anchored within the temporal bone. In a minor surgical procedure this implant is fitted under local anaesthetic. Sound vibration is then transferred from the transducer directly to the skull base thus giving direct bone conduction.

Sensorineural hearing loss is the most common form of hearing impairment. Conductive hearing loss is a second, less common, type of hearing deficit that may be suitable for surgical correction. If not, these patients are usually fitted with either conventional air or bone conduction hearing aids. Difficulties arise when hearing loss is further complicated by chronic otitis media, otitis externa and congenital aural atresia. In these particular situations, an ear mould is difficult or impossible to use. In such patients the introduction of the bone anchored hearing aid has proved to be invaluable.<sup>2,3</sup> Conventional bone conduction hearing aids are a less popular option because of their poor aesthetic appearance, comfort, frequency response and inadequate gain.<sup>2</sup>

In this study patients were asked to compare their current bone anchored hearing aid with their previous conventional hearing aid.

## Patients and Methods

The questionnaire used in this study was first designed, validated and used by Mylanus *et al* in 1998 (Appendix 1).<sup>4</sup>

Table 1. Distribution of response rates

Total number of implantees	351	
Total included in the study	312	(6 months or more of BAHA use)
Total excluded	39	(less than 6 months of BAHA use) (31 adults, 8 children)
Total respondents	227	(72% response rate)
Total non-respondents	85	
Adults (211)	187	respondents (89%)
	24	non-respondents (11%)
Children (101)	40	respondents (40%)
(under 16 years)	61	non-respondents (60%)

The Nijmegen group compared the BAHA to the patients' previous air-conduction hearing aids. However, our study uses the same questionnaire to compare the BAHA to the previous conventional air-conduction (AC) or bone-conductor (BC) aid.

To avoid "enthusiasm" bias and initial difficulties with fitting and maintenance of their bone anchored hearing aid, only those subjects who had worn a bone anchored hearing aid for six months or more were included in this study. A total of 312 patients were sent the postal questionnaire. A waiting period of 4 months was allowed for return of completed questionnaires. A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

The binomial test (data in non-parametric scales) was applied to the results for statistical analysis.

## Results

351 patients were implanted in the BAHA programme. There were 187 males and 164 females. The age range was 2 to 67 years. A total of 312 patients were included in the study. 227 (72%) questionnaires were completed and returned. Of the 85 non-respondents, 61 (72% of 85) were children. Patients that returned completed questionnaires had worn their BAHA for a period of 6 months to 11 years (mean 5.8 years). Table 1 illustrates the distribution of the response rates.

Table 2 Which hearing aid is better with regard to

<u>Parameter</u>	<u>BAHA</u>	<u>AC/BC Aid</u>	<u>Significance</u> (Binomial test)
a Occurrence of ear infections (reduced)	72.8%	2.4%	$p < 0.001$
b Speech recognition – Quiet	79.3%	4.7%	$p < 0.001$
c Speech recognition – Noise	59.2%	6.5%	$p < 0.005$
d Sound Quality	78.7%	8.3%	$p < 0.001$
e Visibility	70.4%	7.7%	$p < 0.001$
f Handling	81.8%	4.7%	$p < 0.001$
g Feedback problems	75.1%	4.7%	$P < 0.001$
h ENT visits	70.4%	3%	$p < 0.001$

BAHA - Bone anchored hearing aid, AC aid - Air conduction aid, BC aid - Bone conductor aid

Patients found the bone anchored hearing aid to be significantly superior in all respects when compared to their previous conventional hearing aids (air-conduction or bone conductor) as depicted in Table 2. 58 patients (25% of 227) had used a bone-conductor (BC aid) at some stage of hearing rehabilitation. 14% of respondents found no difference with regards speech recognition in noisy surroundings and 12% found handling of the BAHA to be similar to their previous aids.

When asked to identify the most positive distinguishing feature of their BAHA, 179 (79%) of 227 respondents believed sound quality to be the most outstanding feature ( $p < 0.001$ ). 163 (72%) respondents were pleased with the reduced number of ear infections ( $p < 0.001$ ). 179 (79%) felt speech in quiet surroundings was improved, and 133 (59%) had similar feelings regarding speech in a noisy environment (Figure 1).

45 (20%) of respondents felt that visibility was the most negative finding. 23 (10%) believed speech in noise and the number of visits to the ENT department to be the most negative aspects of the BAHA (Figure 2).

The health of the titanium implant and the ultimate success of the BAHA depends heavily upon the meticulous care and cleaning of the abutment. The cleaning of the BAHA was not really regarded as a problem by 146 (64%) of respondents ( $p < 0.001$ ) (Figure 3).

Finally, the overwhelming majority of patients 189 (83%) preferred the BAHA ( $p < 0.001$ ) (Figure 4).

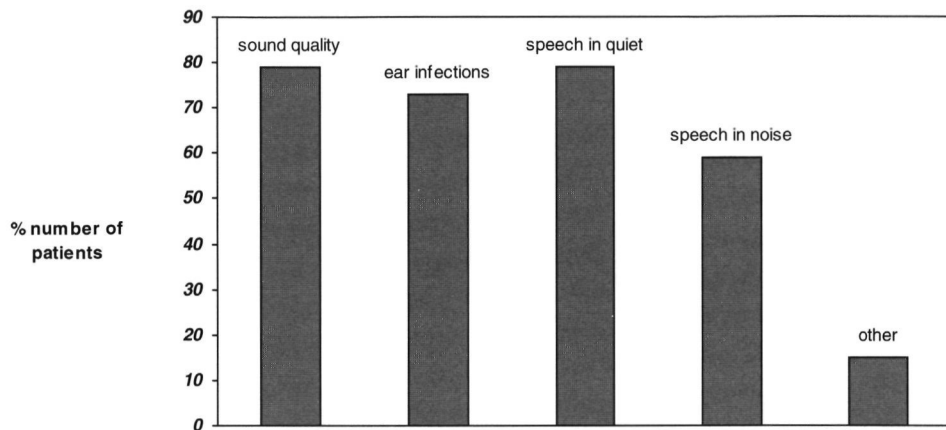


Figure 1. Hearing aid related aspects with which BAHA distinguishes itself in a positive sense

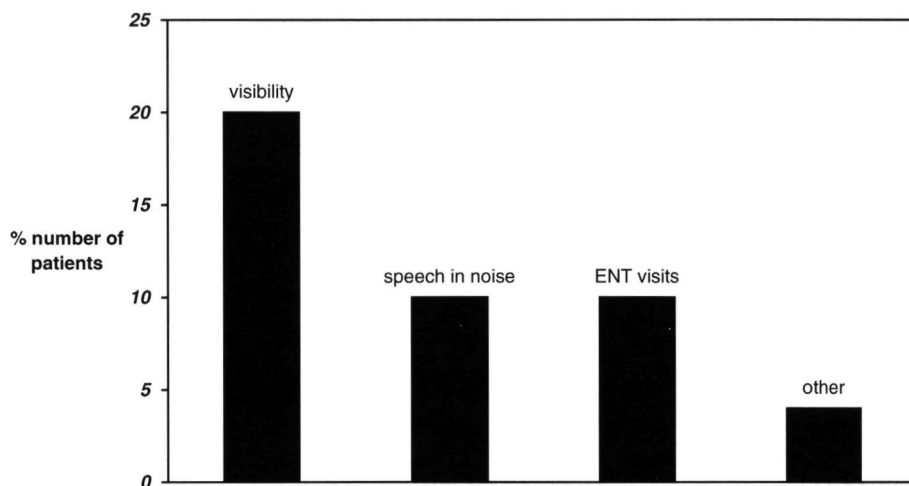


Figure 2. Hearing aid related aspects in which the BAHA distinguishes itself in a negative sense

## Discussion

Bone conduction hearing aids were first described in the 18<sup>th</sup> Century.<sup>5</sup> Today a conventional bone anchored hearing aid consists of a transducer and amplifier attached to a headband or spectacle frame. It is designed to press firmly against the skull vault. These hearing aids have remained unpopular due to their poor aesthetics, discomfort due to constant pressure from the transducer, and poor sound quality at higher frequencies.

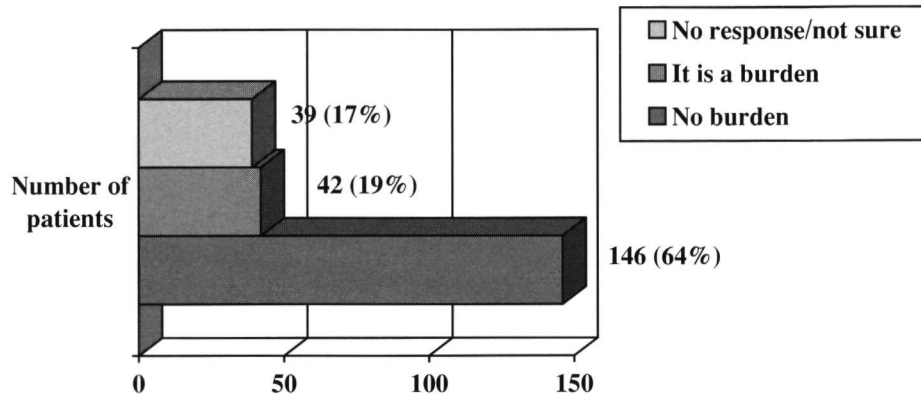


Figure 3. Cleansing and care of the implant site and surrounding skin

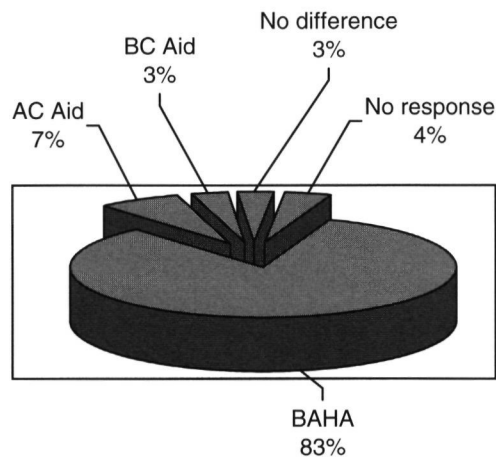


Figure 4. The hearing aid that is preferred the most

BAHA - Bone anchored hearing aid; AC aid - Air conduction aid (conventional); BC aid - Bone conductor aid (conventional)

The alternative bone anchored hearing aid was first described by Hakansson in 1985<sup>1</sup> and became commercially available in 1987. The introduction of this titanium implant system by Branemark represented an important breakthrough in establishing both excellent device retention and also reaction-free penetration of the skin.

Today audiological testing is utilised to evaluate hearing aid performance, however these results do not always correlate to the patients own perception of their hearing aid. This study presents the subjective results of an intra-individual comparison between the bone anchored



hearing aid and previously worn conventional hearing aids (air conduction - AC, or bone-conductor - BC) of patients in the largest BAHA programme in the UK.

Each patient included in the study had worn a bone-anchored hearing aid for a period of 6 months to 11 years (mean 5.8years). Some bias was expected from patients who had worn their bone anchored hearing aid for many years. Memories of previous hearing aids fade with time and may affect the response to the questionnaire. The underlying otological conditions included congenital aural atresia, chronic otitis media, chronic otitis externa, large mastoid cavities, otosclerosis and an intolerance to alternative hearing aids. The model of bone-anchored hearing aid used by each patient was not identified in this study.

Of the 85 non-respondents, 61 (72% of 85) were paediatric patients. The questionnaire does appear to be primarily aimed at the adult patient and questions such as sound quality were difficult for paediatric subjects to both interpret and answer even with help from parents. An attempt to cleave data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e., BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in figures and tables). This data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the Company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

The BAHA was found to be better than both the air and bone conduction hearing aids in all aspects. However, the main advantages appeared to be sound quality and reduced ear infections. Speech in quiet surroundings was also considered to be greatly improved with the use of the bone-anchored aid. These findings are in keeping with published literature.<sup>2,6,7,8</sup>

Visibility of the BAHA was found to be the most negative finding. The number of visits to the out patient clinic and the quality of speech in noise were also believed to be negative factors. Additional patient comments stated that the frequency of outpatient visits was only a problem in the early post operative period.

Cleansing of the BAHA abutment is vitally important if osseointegration is to be maintained. Patients about to undergo implantation are routinely informed of the need of partner co-operation with cleaning the fixture especially in the early post-operative weeks. In this study, cleaning was not found to be a problem to 64% of respondents.

Finally, the overall preference was overwhelmingly found to be for the BAHA over other hearing aid types.

**Conclusions**

73% of patients with previous discharging ears had fewer ear infections with the BAHA 79% of the respondents perceived better speech in quiet and 59% better speech in noise with the BAHA

78% of BAHA users liked the quality of sound with the BAHA 64% of the users did not perceive care of the implant site as a burden An overwhelming 83% of the respondents preferred BAHA to their previous hearing aids

**Acknowledgements**

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**Appendix 1:**

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**The Nijmegen Questionnaire**

An Intra-individual comparison of the Bone Anchored Hearing Aid and previous air conduction hearing aids

1. Which hearing aid is better with regard to -
- |   |  |        |      |               |
|---|--|--------|------|---------------|
| A | Occurrence of ear infections             | AC aid | BAHA | No difference |
| B | Speech recognition in quiet places       | AC aid | BAHA | No difference |
| C | Speech recognition in noisy surroundings | AC aid | BAHA | No difference |
| D | Sound quality                            | AC aid | BAHA | No difference |
| E | Visibility                               | AC aid | BAHA | No difference |
| F | Handling                                 | AC aid | BAHA | No difference |
| G | Feedback problems                        | AC aid | BAHA | No difference |
| H | ENT visits                               | AC aid | BAHA | No difference |
2. On which of these hearing aid related aspects A to H does the BAHA distinguish itself most from the previous hearing aid in a positive sense?
3. On which of these hearing aid related aspects A to H does the BAHA distinguish itself most from the previous hearing aid in a negative sense?
4. Do you regard cleansing of the implant and the surrounding skin as a burden?
5. In general, which hearing aid do you prefer?

AC hearing aid	BAHA	No difference
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Comments

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# Chapter 4

## **Day to day use and service-related issues with the bone anchored hearing aid: The Entific Medical Systems questionnaire**

Sunil N Dutt, Ann -Louise McDermott, Anwen Jelbert, Andrew P Reid, David W Proops

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## Abstract

Over a 12-year period, the Birmingham Implantation Otology unit has implanted more than 300 patients with bone anchored hearing aids (BAHA)

The Entific Medical Systems questionnaire was administered to these patients to evaluate the day to day use of the BAHA, professional needs, after-care, wear and tear concerns and service related issues. Data analysis revealed that most patients used their BAHA for more than 8 hours a day (90% of BAHA users) and every day of the week (93% of BAHA users). A high degree of satisfaction was expressed as regards sound amplification, listening to radio or television news, listening to music, speech perception in quiet conditions, during conversation with one person in noisy surroundings and conversation with family at home. Some degree of difficulty was expressed with the use of the BAHA during conversation with 2 or more people in noisy surroundings. A slow process of perceptual acclimatisation was noticed with the majority of the patients. The majority of patients were pleased with the service as regards care of the wound, BAHA nursing clinics, device repairs and other service-related issues.

## Introduction

As a part of the Birmingham osseointegration programme, bone anchored hearing aids (BAHA) have been implanted in more than 300 patients including adults and children. The overall philosophy of the programme is an integrated evaluation and rehabilitation package that is ably executed by its multi-disciplinary team.<sup>1,2</sup> Bone anchored aids are now more widely used with extended applications. This is besides the congenital deafness cases for which BAHA has become the first treatment of choice.<sup>3</sup>

After more than a decade's experience with the BAHA, the Birmingham team applied instruments of patient satisfaction in the form of questionnaires to all its patient population. One such questionnaire study was the Entific Medical Systems (Nobel Biocare) questionnaire that was modified and administered to the patients to evaluate specific issues such as

- 1 Daily usage of the BAHA
- 2 Wear and tear concerns including device failures, repairs and replacements
- 3 Service related issues including nursing care and out-patient clinic visits

The objective of this study was to ascertain the usefulness of the BAHA as a hearing habilitation device. With this questionnaire, no comparisons were made with the previous conventional air conduction or bone conduction aid or even to a no-aid situation.



## Patients and Methods

The Entific Medical Systems (Nobel Biocare) questionnaire was previously used by the Birmingham team in evaluating a small group of paediatric patients.<sup>1</sup>

A modified version of this instrument was used as a retrospective postal questionnaire survey on 312 of the 351 patients who had used their BAHA for more than 6 months' duration. This was to allow a period of learning with the use of the BAHA and to avoid beginner's enthusiasm and obviate initial difficulties with fitting and maintenance. A period of four months was allowed for return of the questionnaire to the BAHA office.

A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

## Results

Of the 351 patients implanted between 1988 and 1999, 312 were included in the study. A period of 6 months use and familiarity with the BAHA was considered essential for learning and acclimatisation. It was also hoped that this eliminated any enthusiasm bias. There was a 72% response rate with 227 completed questionnaires being returned. Of the 227 respondents, 187 were adults and the rest children as shown in Table 1.

The study addressed three specific areas, viz., day to day use, wear and tear concerns and service issues.

### *Day to day usage:*

The BAHA was most often used all day long by 147 of the 227 (65%) patients. The rest of the patients used the aid for variable periods during the day and some for work only.

Table 1 Distribution of response rates

Total number of implantees	351	(242 adults and 109 children)
Total included in the study	312	(6 months or more of BAHA use)
Number excluded	39	(less than 6 months of BAHA use) (31 adults and 8 children)
Total respondents	227	(72% response rate)
Total non-respondents	85	
Adults (211)	187	respondents (89%)
	24	non-respondents (11%)
Children (101)	40	respondents (40%)
(under 16 years)	61	non-respondents (60%)

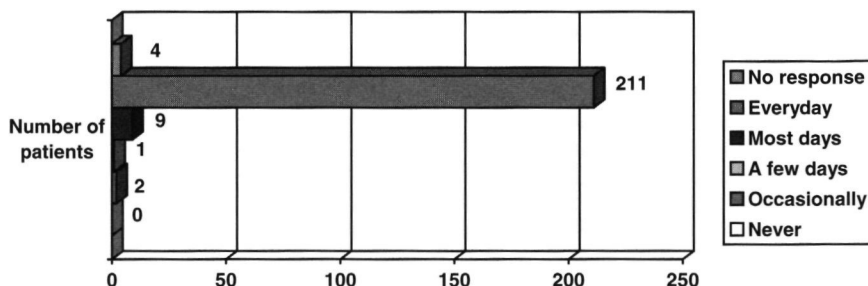


Figure 1. Number of DAYS PER WEEK the BAHA is used

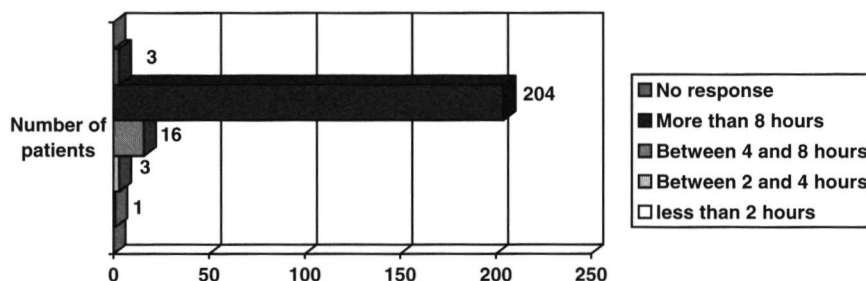


Figure 2. Number of HOURS of BAHA use PER DAY

4.8% (11 of 227) of the patients used their previous aids (air or bone conduction aids) as a temporary measure. These included 7 patients with fixture failures (6 paediatric, 1 adult), 3 patients with wound problems and one awaiting hearing aid replacement. Figure 1 illustrates the number of days per week the BAHA was used and Figure 2 shows the number of hours per day with BAHA use. It is reassuring to note that the majority of them found the BAHA useful for more than 8 hours a day (90% of 227) and for every day of the week (93% of 227). A 185 of the users (81%) were satisfied with the degree of amplification that the BAHA produced (Figure 3). 172 (76%) patients reported that the BAHA was 'quite satisfactory' to 'very satisfactory' when listening to radio and television news (Figure 4). 74% (74+95) of the respondents were pleased with the BAHA when listening to music (Figure 5).

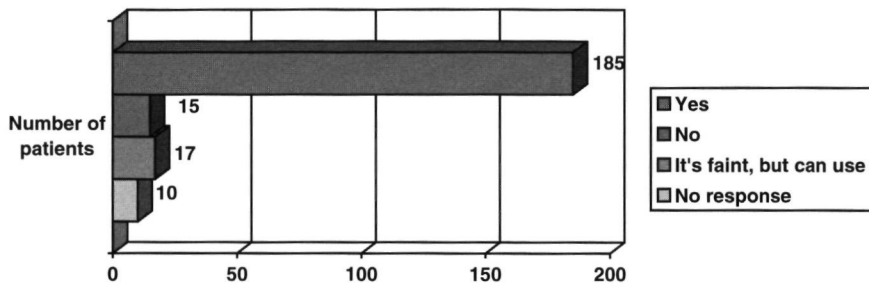


Figure 3. Sound amplification by the BAHA

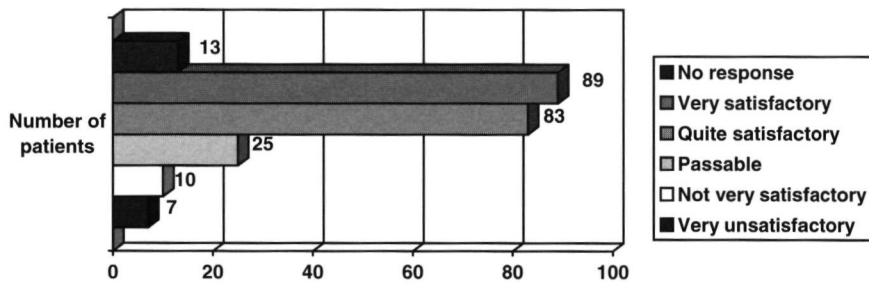


Figure 4. BAHA rating when listening to the radio or television news

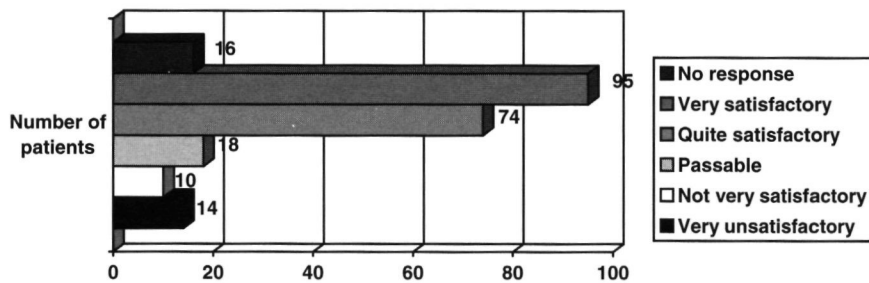


Figure 5. BAHA rating when listening to music

With speech in quiet (Figures 6 and 7), a high degree of satisfaction was expressed by 84% (147+44) of candidates as regards 'conversation with one person in quiet' and by 67% (86+65) of candidates for 'conversation with 2 or 3 people in quiet surroundings'.

The results with speech in noise (Figures 8 and 9) were not that encouraging. 25% and 18% of the patients rated their BAHA as 'passable' with regard to conversation with 'one person in noise' and 'with a group of people in noise' respectively. Only 38% (60+27) were satisfied with the BAHA during conversation with one person in noisy environment. About 50% of the respondents (72+42) rated the BAHA unsatisfactory as regards speech in noise with a group of people (Figure 9). It was interesting to note that most of these 'unsatisfied' patients had used their BAHAs for less than 3 years. However, speech in noise in a more familiar environment such as 'family and friends at home' elicited a higher degree of satisfaction (69%) with the BAHA (Figure 10).

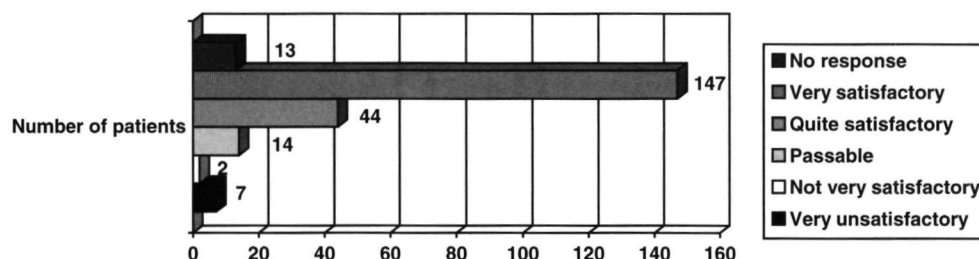


Figure 6. BAHA rating during conversation with 1 person in quiet surroundings

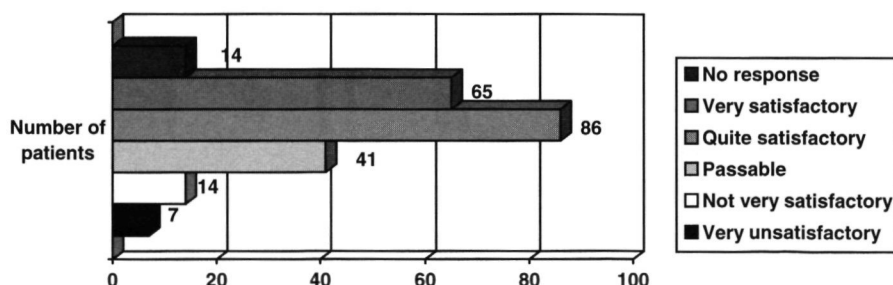


Figure 7. BAHA rating during conversation with 2 or 3 people in quiet surroundings

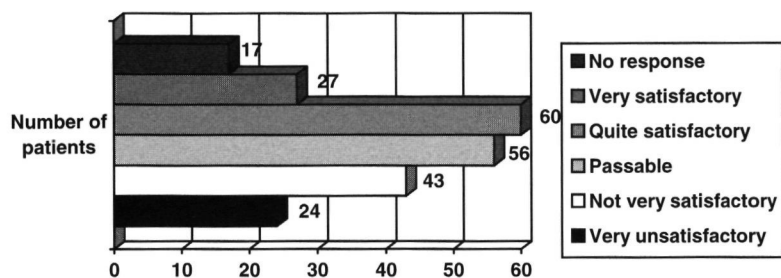


Figure 8. BAHA rating during conversation with 1 person in noisy surroundings

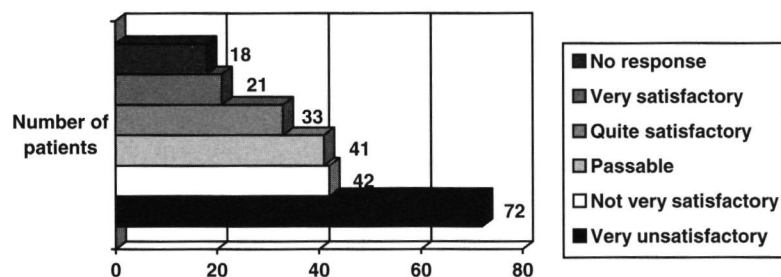


Figure 9. BAHA rating during conversation with a group of people in noisy surroundings

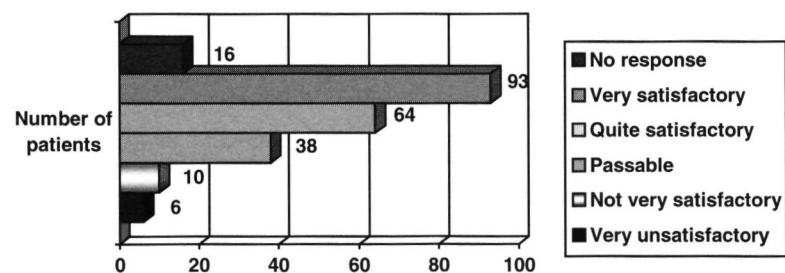


Figure 10. BAHA rating being with family or friends at home

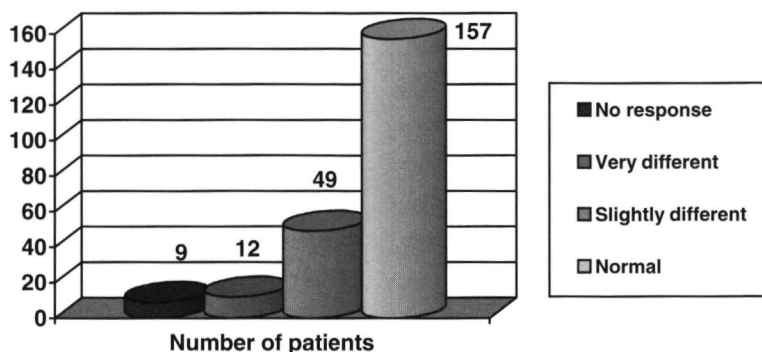


Figure 11. How does your own voice sound when you are using the BAHA?

69% of the respondents perceived no difference with the quality of their own voice with the use of the BAHA (Figure 11). A small percentage (5%) perceived their own voices as 'resonant' or 'robotic' with the BAHA.

Patients who had used their BAHA for more than 3 years (143 of 227) were satisfied with the amplification, sound quality and situational uses than those who had been implanted more recently (less than 3 years).

#### *Wear and tear concerns*

Tables 2 and 3 list the subjective feelings of the patients with the use of the BAHA and the sound produced by the aid respectively. On a satisfaction scale of 1 to 10, the majority of the patients scored in the range of 7 to 10.

89% of the patients were pleased with the repairs and replacement service by the audiological team and the company.

Manual dexterity was an issue with some of the patients (4%) but the majority of them had a helping hand (question 2) in their environment.

Care of the wound, the fixture-abutment assembly and the BAHA was a problem with a minority of patients (9%) and these were mostly children.

92% of the patients required battery changes once a month or longer. Questions on telecoil use and the use of the Bicos produced variable responses. 15% used the telecoil system and 20% used the Bicos in public places and social gatherings.

Table 2 *Word or phrase that best describes your present feelings about your BAHA and its use (one or more options possible)*

Difficult to put in	26	Unnecessary	10
Conspicuous	44	A very great help	152
Tiring	12	Reduces stress	102
Makes me feel awkward	19	Easy to use	156
Not very helpful	7	Very useful in company	116
Noisy	10	Invaluable	142
Difficult to use	3	Wish I had obtained one earlier	160
Uncomfortable	6		

Table 3 *Word or phrase that best describes your present feelings about the sound produced by your BAHA (one or more options possible)*

Soft/pleasant	63	High/thin	5
Hard/sharp/blaring	29	Deep/dull	3
Natural/clear/pure	113	Muffled	18
Impure	10	Echoing	18
Uncomfortably loud	8	Crackling	18
Far too weak	21	Others	14

### *Service related issues*

A small percentage (3%) of patients were dissatisfied with the surgical aspects. These were patients who presented with wound problems and fixture failures.

An overwhelming 94% of the respondents were satisfied with the nursing care and the ward staff. 2% of the patients were dissatisfied with the waiting times in the specialist out-patient clinics and at the audiology services.

## Discussion

The selection protocol, referral practice and rehabilitation regimens for both adult and paediatric groups of patients on the Birmingham BAHA programme have been extensively discussed earlier <sup>1 2</sup> Two other pioneering centres of BAHA implantation i.e., Gothenburg and Nijmegen have published their long-term results with encouraging outcomes <sup>3 4</sup>

The questionnaire used is a modification of the one previously produced by the Nobel Biocare company and evaluated by the Birmingham team <sup>1</sup>

A 72% response rate is significant and adds value to the results. Individual questions in the questionnaire have a small 'no response' rate and these were attributed to

- 1 question not applicable to the candidate and
- 2 some of the paediatric group who perhaps did not seek help from their parents in completing the questionnaire

Cleaving data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. However, 72% of the non-respondents were children (Table 1). Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e., BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in figures and tables). This data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the Company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

A high degree of satisfaction was expressed by most patients using the BAHA and these results are comparable to published literature from other centres <sup>5 6</sup>

In many of the day-to-day situations, the candidates perceived a certain degree of learning process. Some patients who were extremely dissatisfied with their previous conventional aids were overwhelmed by the benefits of the BAHA soon after fitting. To obviate this enthusiasm bias and allow a natural trial and learning process, the team chose to test and question only those patients who had used their BAHA for longer than six months. As mentioned, it appeared that patients who had used the BAHA for more than 3 years were satisfied with the amplification, sound quality and situational uses as above than those who had been implanted more recently. This was the gradual process of perceptual acclimatisation that was expected.



The Birmingham BAHA team includes two specialist BAHA nurses in the adult programme and an advanced nurse practitioner in the paediatric service. They have been involved in the management of dressings, wound care and care of the fixture-abutment assembly. 94% of the respondents were extremely pleased with this service and the nursing care they received during their surgeries. With surgery, a one stage complete procedure under local anaesthetic for adults and a two stage procedure under general anaesthetic for children is the norm as described previously.<sup>3</sup>

Most of the patients were pleased with the care and time allocated for them in the multidisciplinary specialist BAHA and FAITEC (Facial and Audiological Implantation Technology) clinics. Outpatient attendance for suction clearance of draining ears was understandably reduced in a number of patients whose mastoid cavities and perforated ears were rendered dry.<sup>9,10</sup>

Audiological services include a robust pre-assessment protocol, post-implantation periodic evaluation and liaison for repairs, battery changes, replacements with the Entific Medical Systems. The service of specialist speech and language therapists is also available on both the adult and paediatric teams.<sup>11</sup> Most patients were quite satisfied with these services, however there were a few less satisfied individuals.

## **Conclusions**

In summary, a high degree of satisfaction was expressed by most of the respondents with the use of the BAHA in their day to day activities at home and at work.

The majority of the respondents were pleased with the care and service provided by the multidisciplinary teams involved.

## Appendix 1:

### The Entific Medical Systems (Nobel Biocare) Questionnaire

- 1 The hearing aid most often used - previous AC/BC aid BAHA
- 2 At home, do you often have someone in your immediate vicinity, e.g. husband/wife/children/mother/father/sister/brother etc Yes/ No
- 3 How many days per week do you use your hearing aid?
  - 1 Every day ---
  - 2 Most days ---
  - 3 A few days ---
  - 4 Only occasionally ---
  - 5 Never ---
- 4 How many hours would you say that you use your hearing aid during the course of a normal day?
  - 1 Less than two hours ---
  - 2 Between two and four hours ---
  - 3 Between four and eight hours ---
  - 4 More than eight hours ---
- 5 How often do you change the battery?
 

(Type of battery Zinc/Mercury/Other)

  - 1 Once a week ---
  - 2 Twice a month ---
  - 3 Every three weeks ---
  - 4 Once a month ---
- 6 Does your hearing aid amplify sound sufficiently?
  - 1 Yes ---
  - 2 No ---
  - 3 It's faint but I can use it ---
- 7 How would you rate your hearing aid in the following situations?
  - 1 Very satisfactory Score 5
  - 2 Quite satisfactory Score 4
  - 3 Passable Score 3
  - 4 Not very satisfactory 2
  - 5 Very unsatisfactory 1
  - a) When listening to the radio or TV news ---
  - b) When listening to music ---
  - c) Conversation with 1 person in quiet surroundings ---
  - d) Conversation with 1 person in noisy surroundings ---
  - e) Conversation with 2 or 3 people in quiet surroundings ---
  - f) Being with family or friends at home ---
  - g) Being with a group of people in noisy surroundings ---
- 8 How does your own voice sound when you are using your hearing aid?
  - 1 Normal ---
  - 2 Slightly different ---
  - 3 Very different ---

9. Please tick the word or phrase, which best describes your present feelings about your hearing aid and its use (you may tick more than one)

- |                                   |     |
|-----------------------------------|-----|
| 1. Difficult to put in            | --- |
| 2. Conspicuous                    | --- |
| 3. Tiring                         | --- |
| 4. Makes me feel awkward          | --- |
| 5. Not very helpful               | --- |
| 6. Noisy                          | --- |
| 7. Difficult to use               | --- |
| 8. Uncomfortable                  | --- |
| 9. Unnecessary                    | --- |
| 10. A very great help             | --- |
| 11. Reduces stress                | --- |
| 12. Easy to use                   | --- |
| 13. Very useful in company        | --- |
| 14. Invaluable                    | --- |
| 15. Wish I'd obtained one earlier | --- |

Remarks

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10. Please tick the word or phrase, which best describes your present feelings about the sound produced by your hearing aid

- |                              |     |
|------------------------------|-----|
| 1. Soft/pleasant             | --- |
| 2. Hard/sharp/blaring        | --- |
| 3. Natural/clear/pure        | --- |
| 4. Impure                    | --- |
| 5. Uncomfortably loud        | --- |
| 6. Far too weak              | --- |
| 7. High/thin                 | --- |
| 8. Deep/dull                 | --- |
| 9. Muffled                   | --- |
| 10. Echoing                  | --- |
| 11. Crackling                | --- |
| 12. Others (please describe) | --- |

Remarks

-----

-----

-----

11. Please try to indicate how satisfied you are with your present hearing aid by giving it a mark out of 10

1 = very dissatisfied                      10 = very satisfied                      -----

12. Please give your views whether positive or negative on your present hearing aid and the service that has been provided

Audiology service and advice

-----

Battery replacements

-----

---

Device repairs and replacements

---



---

Surgical procedure

---



---

Nursing service

---



---

Ward care

---



---

Outpatient clinic visits and care

---

13 Do you have a Bicros?

Yes/No

If yes,

Do you use the additional microphone?

Yes/No

Situations used in and reasons for not using

---



---



---

14 Do you use the telecoil function?

Yes/No

Situations used in or reasons for not using

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15 Does the BAHA satisfy your professional needs? Yes/ No/ Not applicable

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# Chapter 5

## **Disability, Handicap and Benefit analysis with the bone anchored hearing aid - The Glasgow Hearing Aid Benefit and Difference Profiles**

Ann-Louise McDermott, Sunil N Dutt, Elia Tziambazis, Andrew P Reid, David W Proops

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## **Abstract**

The Birmingham bone-anchored hearing aid programme began in 1988 and by Autumn 2000 a total of 351 patients had been fitted with such an aid. The aim of this study was to assess the effectiveness of hearing rehabilitation with the bone anchored hearing aid.

This was a prospective interview-based questionnaire study carried out in the Autumn 2000. A total of 84 adult patients were interviewed. Each patient had worn their BAHA for more than one year.

The questionnaire used during these interviews was the Glasgow Hearing Aid Benefit Profile (GHABP) and The Glasgow Hearing Aid Difference Profile (GHADP). This was first derived and validated by Gatehouse in 1999. The use of bone anchored hearing aids was found to reduce the level of disability and handicap and provided the most patient benefit and satisfaction.

## **Introduction**

The rehabilitation of patients with hearing loss aims to reduce the level of disability and handicap that occurs as a consequence. Various hearing aids are used to provide amplification and each of these has its own individual problems. Since the advent of the bone-anchored hearing aid (BAHA), it has been shown to be a highly effective hearing aid for patients particularly those with aural atresia, chronic otitis media or externa and more recently otosclerosis.<sup>1,2,3</sup> It has proved to be extremely well tolerated by patients.

The BAHA was first described in the early 1980s and since then the operative techniques employed have evolved along with the hearing aid device itself. It is currently a single stage procedure in adults that can be performed under local anaesthesia. More recently, the advent of the compact BAHA has further improved the aesthetics of wearing such a device.

A series of postal questionnaire studies were undertaken to evaluate patient satisfaction and quality of life with the BAHA.<sup>4,6</sup> However, a prospective interview based questionnaire was necessary to quantify the BAHA use, the residual hearing disability and handicap, overall benefit and patient satisfaction.

## **Patients and methods**

This was a prospective interview-based study using the Glasgow Hearing Aid Benefit and Difference Profiles (GHABP and GHADP). It was designed by Gatehouse in 1999, to evaluate hearing disability, handicap, hearing aid use and benefit, residual disability and patient satisfaction with their hearing aids.<sup>7</sup>



The initial questionnaire provided four predetermined environments and allowed the opportunity for patients to choose a further four situations in which they had hearing difficulties (Appendix 1) The four predetermined situations assessed were the following

- 1 Listening to the television with other family and friends when the volume is adjusted to suit other people
- 2 Having a conversation with one other person when there is no background noise
- 3 Carrying on a conversation in a busy street or shop
- 4 Having a conversation with several people in a group

The first four questions addressed the benefit of a no hearing aid situation with conventional hearing aids i.e. Glasgow Benefit Hearing Aid Profile (GHABP) The second questionnaire used the same four situations except these questions were designed to address the difference between conventional aids and BAHA i.e. Glasgow Hearing Aid Difference Profile (GHADP) (Appendix 2)

The GHABP covered initial disability, handicap, hearing aid use, hearing aid benefit, residual disability and satisfaction This prospective interview-based questionnaire study was carried out in the Autumn 2000 at the Queen Elizabeth Hospital, Birmingham

A total of 84 adult patients who attended the routine follow-up clinics were interviewed Each patient had worn their BAHA for more than one year This was to reduce enthusiasm bias when first issued with their hearing aid

These patients were all randomly selected on the basis of their regular review appointment during a six months' period No paediatric patients were interviewed for this study The same clinician interviewed all subjects included in the study

Scoring of the GHABP and GHADP questionnaires was carried out as recommended in the GHABP- Information Package<sup>7</sup> The scores from each of the four situations were added for each patient and the mean calculated for each set of data The values were then scaled to lie between 0 and 100 by subtracting 1 from each of them and then multiplying by 25

The results were computed using the SPSS package These have been represented in 'Box and Whisker' plots with median values, interquartile ranges (within the box) and highest and lowest data scores (within whiskers) with outliers, if any

## Results

A total of 84 adult patients were interviewed using the GHABP and GHADP Patients involved in the study were all interviewed following a routine out-patient review The age range was 31 to 58 years (mean 46 years) The gender distribution was equal In all cases,

patients volunteered many of their own situations (data not in tables and figures) but most felt the four pre-specified situations encompassed their main difficulties.

The first part of the questionnaire addressed the issue of a no hearing aid situation compared with their conventional air conduction (AC) or bone conductor (BC) hearing aid. In each situation there was considerable disability and handicap but with full time use of a conventional hearing aid, the residual disability was reduced and derived benefit was improved (Tables 1-4)

Table 1 Distribution of scores from Question 1 of the GHABP interview: No hearing aid versus Conventional aid: *Listening to the television with other family or friends when the volume is adjusted to suit other people*

Percentile	Initial Disability	Initial Handicap	Reported Aid Use	Reported Benefit	Residual Disability	Patient Satisfaction
25th	4.0	4.0	5.0	2.0	3.0	2.25
75 <sup>th</sup>	5.0	5.0	5.0	3.0	4.0	3.0
Median	5.0	4.5	5.0	2.0	3.0	3.0

Table 2 Distribution of scores from Question 2 of the GHABP interview: No hearing aid versus Conventional aid: *Having a conversation with one person when there is no background noise*

Percentile	Initial Disability	Initial Handicap	Reported Aid Use	Reported Benefit	Residual Disability	Patient Satisfaction
25th	3.0	3.0	5.0	2.0	2.0	2.0
75 <sup>th</sup>	4.75	5.0	5.0	4.0	3.0	4.0
Median	3.0	4.0	5.0	2.0	3.0	3.0

Table 3 Distribution of scores from Question 3 of the GHABP interview: No hearing aid versus Conventional aid: *Carrying on a conversation in a busy street or shop*

Percentile	Initial Disability	Initial Handicap	Reported Aid Use	Reported Benefit	Residual Disability	Patient Satisfaction
25th	3.0	3.0	5.0	1.0	3.0	1.0
75 <sup>th</sup>	5.0	5.0	5.0	2.75	5.0	3.0
Median	4.0	4.0	5.0	2.0	4.0	2.0

Table 4. Distribution of scores from Question 4 of the GHABP interview: No hearing aid versus Conventional aid. *Having a conversation with several people in a group*

Percentile	Initial Disability	Initial Handicap	Reported Aid Use	Reported Benefit	Residual Disability	Patient Satisfaction
25 <sup>th</sup>	4.0	4.0	5.0	1.0	4.0	1.0
75 <sup>th</sup>	5.0	5.0	5.0	3.0	5.0	2.0
Median	4.0	4.0	5.0	2.0	4.0	2.0

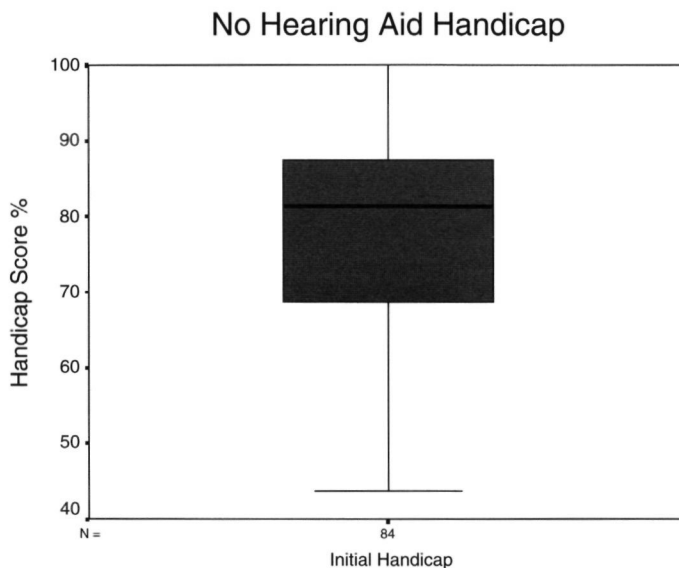


Figure 1. Hearing handicap reported by patients when not using any hearing aid (Box and Whiskers Plot)

The initial hearing disability and handicap was considered to be very significant. A GHABP score ranged from 44 to 100% handicap (Figure 1, Whisker plot). The majority (interquartile range) described a no-hearing aid handicap score of 68 to 88% (Figure 1, Box plot). When asked about the amount of time these conventional hearing aids were used it appeared the vast majority wore their aids all of the time (Figure 2). Only five patients reported wear for less than three quarters of the time. Despite this use, the hearing benefit was surprisingly poor, with a GHABP benefit score range of 28 to 38% (Figure 2). It was found that overall, the hearing disability was less with conventional aids compared to the initial disability (Figure 3).

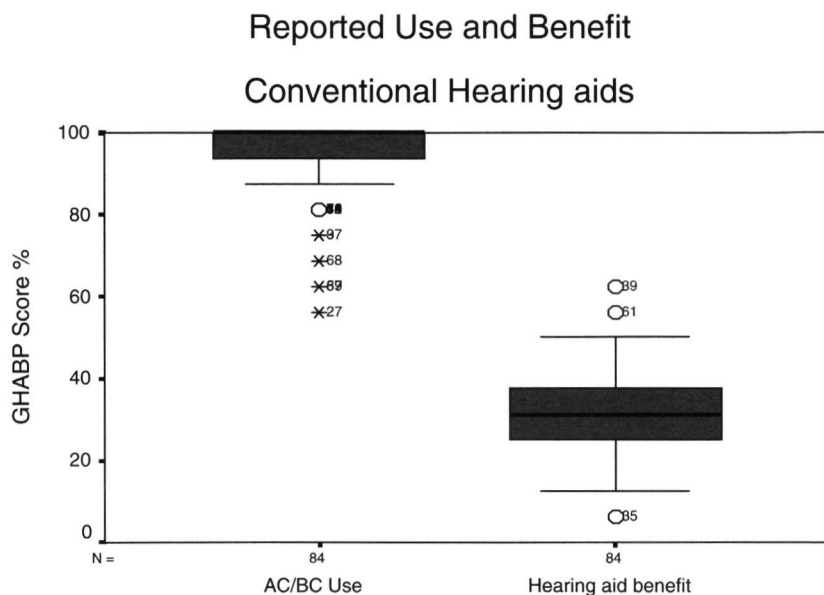


Figure 2. GHABP scores showing the use of conventional hearing aids and the benefit these hearing aids provide

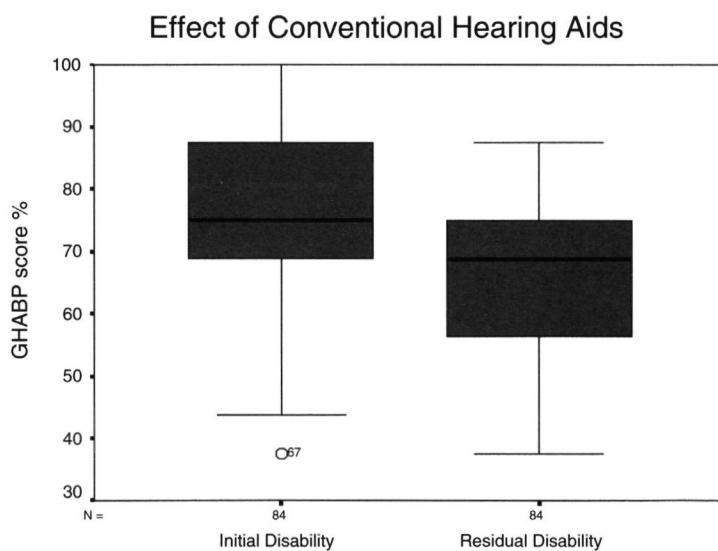


Figure 3. Hearing disability before and after wearing conventional hearing aids

Table 5 Distribution of scores from Question 1 of the GHADP Profile Conventional aid versus BAHA  
*Listening to the television with other family or friends when the volume is adjusted to suit other people*

Percentile	Initial Disability with Previous Aid	Reported Previous Aid Use	Reported BAHA Use	Reported Benefit with BAHA	Residual Disability with BAHA	Patient Satisfaction with BAHA
25 <sup>th</sup>	3 0	4 0	5 0	5 0	1 0	4 0
75 <sup>th</sup>	4 0	5 0	5 0	5 0	1 0	5 0
Median	3 0	4 0	5 0	5 0	1 0	5 0

Table 6 Distribution of scores from Question 2 of the GHADP Profile Conventional aid versus BAHA  
*Having a conversation with one person when there is no background noise*

Percentile	Initial Disability with Previous Aid	Reported Previous Aid Use	Reported BAHA Use	Reported Benefit with BAHA	Residual Disability with BAHA	Patient Satisfaction with BAHA
25 <sup>th</sup>	3 0	4 0	5 0	5 0	1 0	5 0
75 <sup>th</sup>	5 0	5 0	5 0	5 0	1 0	5 0
Median	4 0	5 0	5 0	5 0	1 0	5 0

Table 7 Distribution of scores from Question 3 of the GHADP Profile Conventional aid versus BAHA  
*Carrying on a conversation in a busy street or shop*

Percentile	Initial Disability with Previous Aid	Reported Previous Aid Use	Reported BAHA Use	Reported Benefit with BAHA	Residual Disability with BAHA	Patient Satisfaction with BAHA
25 <sup>th</sup>	4 0	5 0	5 0	3 0	2 0	4 0
75 <sup>th</sup>	5 0	5 0	5 0	4 0	3 0	5 0
Median	4 5	5 0	5 0	3 0	3 0	4 0

Table 8 Distribution of scores from Question 4 of the GHADP Profile Conventional aid versus BAHA  
*Having a conversation with several people in a group*

Percentile	Initial Disability with Previous Aid	Reported Previous Aid Use	Reported BAHA Use	Reported Benefit with BAHA	Residual Disability with BAHA	Patient Satisfaction with BAHA
25 <sup>th</sup>	4 0	4 0	5 0	3 0	2 0	4 0
75 <sup>th</sup>	5 0	5 0	5 0	5 0	3 0	5 0
Median	4 0	5 0	5 0	4 0	2 0	4 0

The second part of the study compared conventional air or bone conduction hearing aids with the BAHA (GHADP). Compliance with BAHA use was excellent and the benefit, reduced hearing disability and overall satisfaction was significantly improved when compared to other aids (Tables 5-8).

Firstly, the day to day usage of each type of hearing aid was similar with the majority of patients wearing their aids all of the time (Figure 4). The residual hearing disability was markedly reduced with the use of a BAHA and this was found to be significant (Figure 5). The benefit of BAHA use was greater than conventional aids (Figure 6), and patient satisfaction was significantly better with the use of BAHA compared to conventional aids (Figure 7). BAHA use was encouraging and the benefit was significantly better than that of prior aids (Figure 8). Finally, the regular use of a BAHA significantly reduced the level of hearing disability compared to both conventional aid use and a no-aid situation (Figure 9).

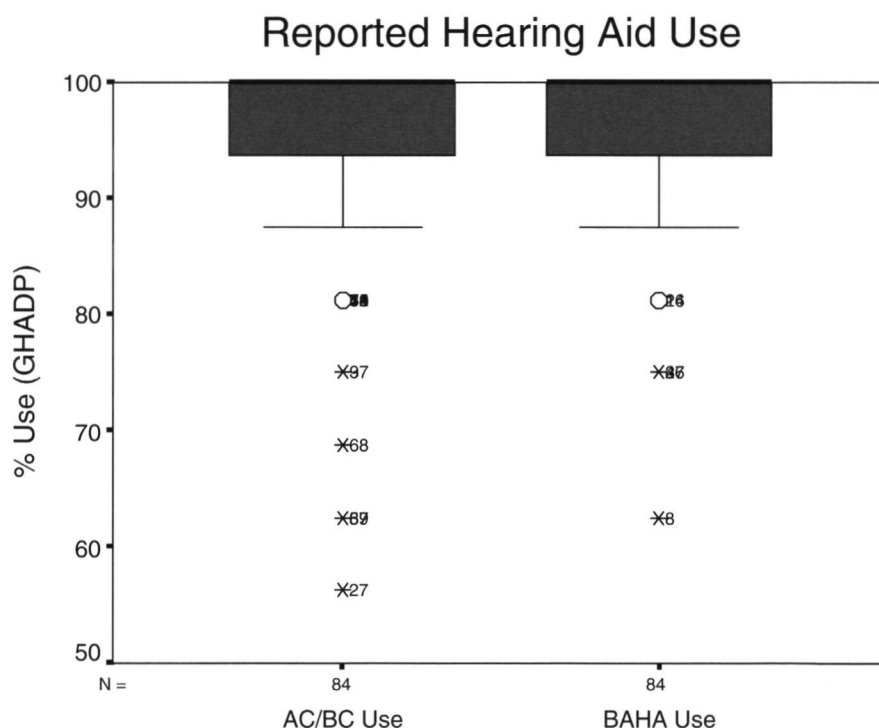


Figure 4. Day-to-day use of hearing aids - the current BAHA and previous conventional hearing aid

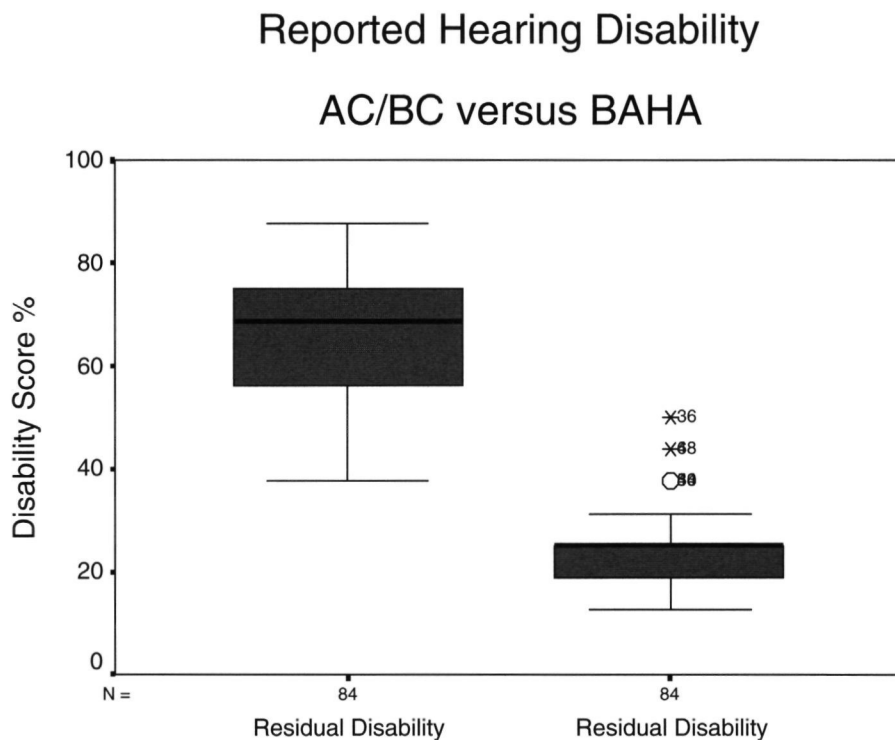


Figure 5. Residual disability after conventional hearing aid compared with the use of a BAHA

## Discussion

Hearing aid services may be configured in a variety of ways but always contain elements associated with the technical performance of the device and the extent to which it helps the listener overcome the deficits and disadvantages experienced in everyday life. In the context of optimising services, there is a growing requirement to provide measures of outcome that are appropriate and sensitive to the various options for intervention. It is essential to demonstrate these measures of outcome to bodies or individuals responsible for funding services and to the hearing-impaired listeners.<sup>7</sup>

Performance measures cannot adequately characterise disability and handicap and therefore such instruments have stayed in the self-reporting domain. This has led to the development of a variety of questionnaires and inventories for the characterisation of disability and handicap and its subsequent change following intervention.<sup>8-10</sup>

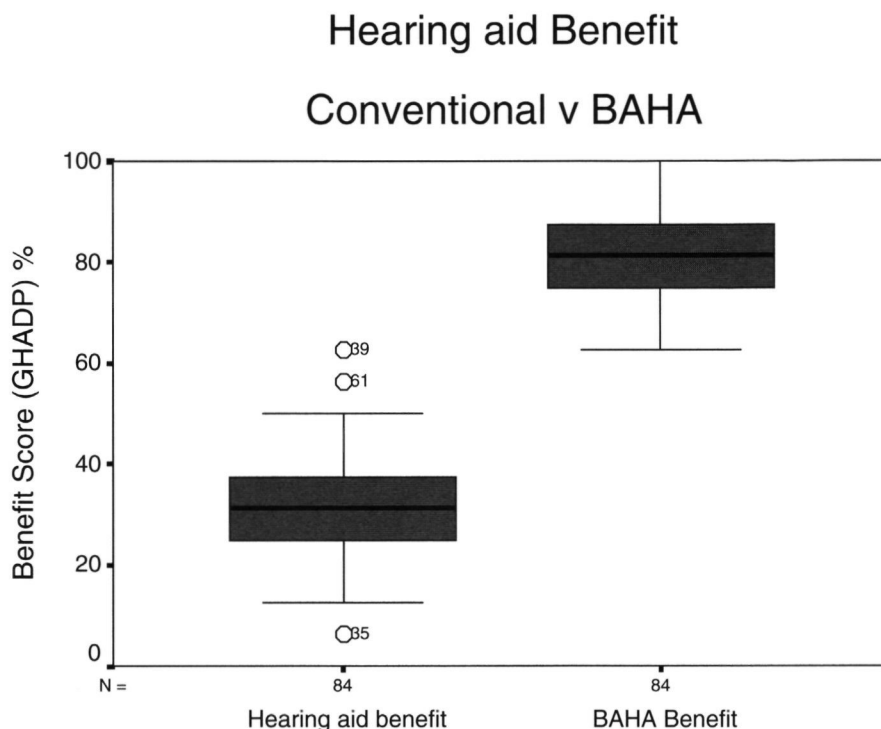


Figure 6. Differences in the benefit obtained by conventional aid and BAHA use

The Glasgow Hearing Aid Benefit Profile is one such client-centred questionnaire. It has been derived, optimised and verified as an instrument suitable for application in the context of evaluation of efficacy and effectiveness of rehabilitation services for hearing-impaired adults. The GHABP firstly assesses four pre-specified listening circumstances which commonly occur in the lives of the hearing-impaired (Appendix 1). These are separately assessed as to

- (i) their occurrence,
- (ii) their degree of difficulty experienced by the listener (initial disability),
- (iii) the effect or impact on the hearing-impaired listener's life (handicap),
- (iv) the extent to which the hearing aid is used in that listening circumstance (reported HA use),
- (v) the extent to which hearing is improved in that listening circumstance (hearing aid benefit),



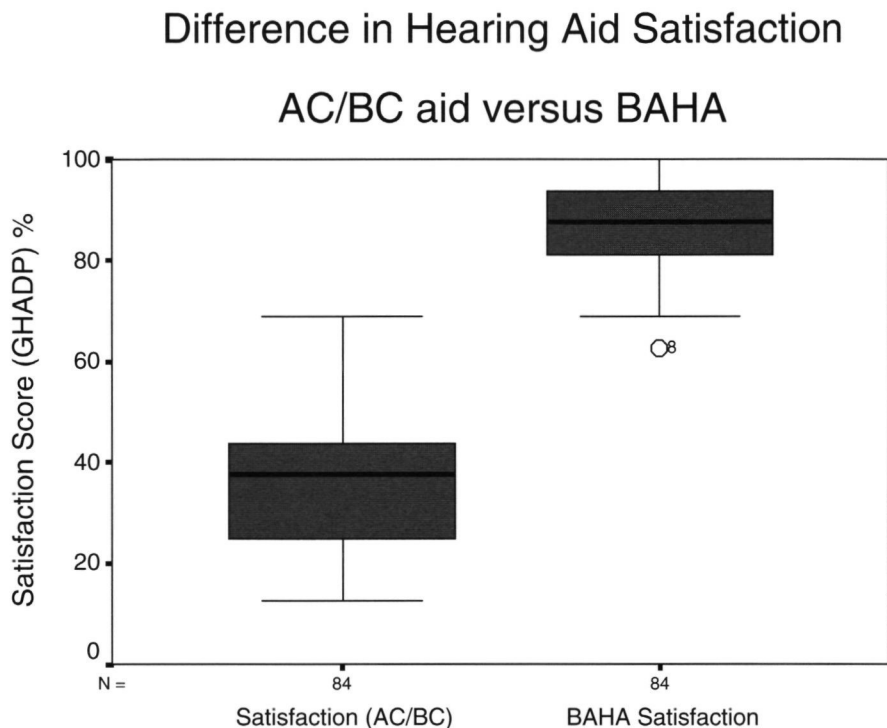


Figure 7. Patient satisfaction with the conventional aid compared with the BAHA

- (vi) the hearing difficulty experienced by the listener after the fitting of the hearing aid (residual disability) and
- (vii) the client's satisfaction with their hearing aid for that listening circumstance.

Another page (not shown in appendix) on the GHABP allows the listener to specify up to four additional listening circumstances of importance and relevance to their everyday communication circumstances, for example, listening to music, having a conversation on the telephone and following a lecture or service in church. Some of the patients in our series (14% of 84) chose to discuss listener specified situations as mentioned above. However, all 84 of them agreed that the four pre-specified situations reflected the disabilities and benefits quite satisfactorily.

This is then followed by the Difference Profile (GHADP; Appendix 2) that compares the previous hearing aid with a new hearing aid with respect to the previously described domains.

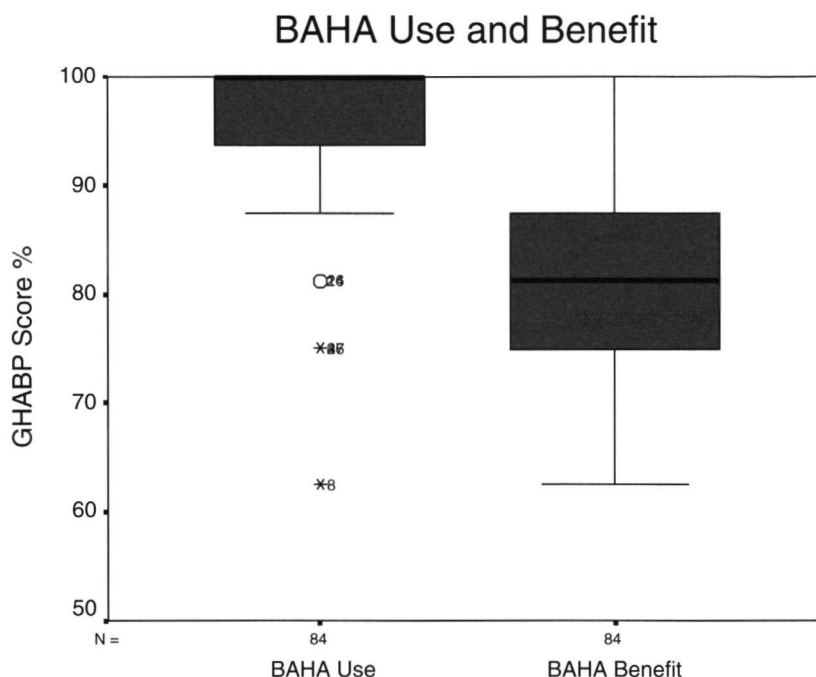


Figure 8. Compliance with BAHA use and perceived benefit

The GHABP has been optimised and validated previously. Our study is the first to evaluate the use of bone anchored hearing aids using GHABP. Needless to say that the questionnaire is designed to be completed by an independent observer in an office-setting and is not suitable for postal surveys. The GHABP and the GHADP proved to be valuable tools (prospective interview based questionnaires) in the evaluation of our hearing aid services. It is envisaged that the instrument will be applied to all the patients on the Birmingham BAHA programme who are on regular audiological follow-up.

## Conclusions

84 BAHA users were evaluated using the GHABP and the hearing disability was significantly reduced with the BAHA compared to their previous conventional hearing aids. The reported hearing aid benefit and patient satisfaction were higher with the BAHA compared with the previous aids.

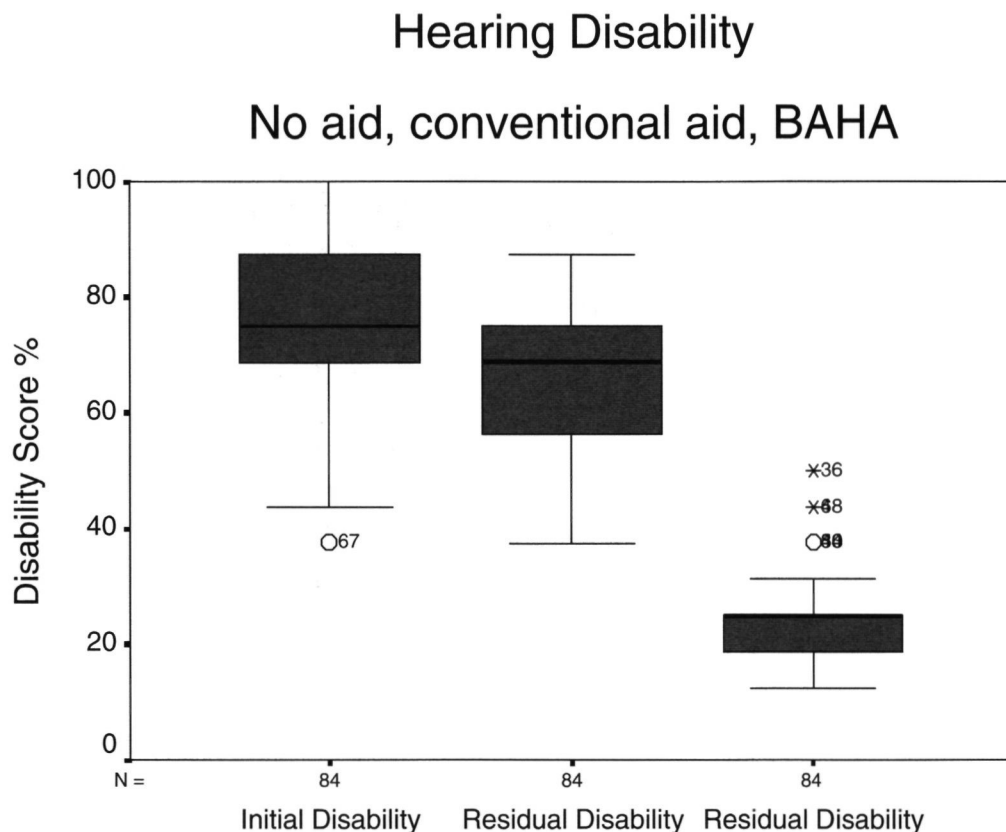


Figure 9. Disability without aid, with conventional hearing aid and with the BAHA

This prospective study on 84 BAHA users demonstrates that the GHABP is a suitable candidate for a routine service-monitoring indicator as part of a program of quality assurance and standards.

#### Acknowledgements

We are grateful to Miss Joanne Foster, BSc, PhD, Research and Development Department, Postgraduate Centre, Stepping Hill Hospital, Stockport, UK and Professor Stuart Gatehouse, Institute of Hearing Research, Glasgow, UK for their invaluable input in the preparation of this paper.

## Appendix 1:

## The Glasgow Hearing Aid Benefit Profile (GHABP)

## GLASGOW HEARING AID BENEFIT PROFILE

Date of Assessment

Date of Review .....

Hospital Number.....

Name .....

Address .....

Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE</b>			
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, <u>with your hearing aid</u> , how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE</b>			
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, <u>with your hearing aid</u> , how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP</b>			
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, <u>with your hearing aid</u> , how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid

Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP</b>			
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, <u>with your hearing aid</u> , how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid

## Appendix 2:

## The Glasgow Hearing Aid Difference Profile (GHADP)

## GLASGOW HEARING AID DIFFERENCE PROFILE

Date of Assessment

Date of Review

Hospital Number.....

Name .....

Address .....

Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE</b>			
With your <u>current</u> hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your <u>current</u> hearing aid?	In this situation, with your <u>new</u> hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your <u>new</u> hearing aid?	In this situation, how much <u>more</u> does your <u>new</u> hearing aid help compared to your previous one?	For this situation, how much <u>more</u> satisfied are you with your <u>new</u> aid than with your previous one?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ New aid much worse 2 ___ New aid worse 3 ___ New aid the same 4 ___ New aid better 5 ___ New aid much better	0 ___ N/A 1 ___ Much less satisfied 2 ___ Less satisfied 3 ___ Equally satisfied 4 ___ More satisfied 5 ___ Much more satisfied
Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE</b>			
With your <u>current</u> hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your <u>current</u> hearing aid?	In this situation, with your <u>new</u> hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your <u>new</u> hearing aid?	In this situation, how much <u>more</u> does your <u>new</u> hearing aid help compared to your previous one?	For this situation, how much <u>more</u> satisfied are you with your <u>new</u> aid than with your previous one?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ New aid much worse 2 ___ New aid worse 3 ___ New aid the same 4 ___ New aid better 5 ___ New aid much better	0 ___ N/A 1 ___ Much less satisfied 2 ___ Less satisfied 3 ___ Equally satisfied 4 ___ More satisfied 5 ___ Much more satisfied
Does this situation happen in your life? 0 ___ No                      1 ___ Yes		<b>CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP</b>			
With your <u>current</u> hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your <u>current</u> hearing aid?	In this situation, with your <u>new</u> hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your <u>new</u> hearing aid?	In this situation, how much <u>more</u> does your <u>new</u> hearing aid help compared to your previous one?	For this situation, how much <u>more</u> satisfied are you with your <u>new</u> aid than with your previous one?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ New aid much worse 2 ___ New aid worse 3 ___ New aid the same 4 ___ New aid better 5 ___ New aid much better	0 ___ N/A 1 ___ Much less satisfied 2 ___ Less satisfied 3 ___ Equally satisfied 4 ___ More satisfied 5 ___ Much more satisfied

Does this situation happen in your life? 0 ___ No                      1 ___ Yes		HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP			
With your <u>current</u> hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your <u>current</u> hearing aid?	In this situation, with your <u>new</u> hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your <u>new</u> hearing aid?	In this situation, how much <u>more</u> does your <u>new</u> hearing aid help compared to your previous one?	For this situation, how much <u>more</u> satisfied are you with your <u>new</u> aid than with your previous one?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ New aid much worse 2 ___ New aid worse 3 ___ New aid the same 4 ___ New aid better 5 ___ New aid much better	0 ___ N/A 1 ___ Much less satisfied 2 ___ Less satisfied 3 ___ Equally satisfied 4 ___ More satisfied 5 ___ Much more satisfied

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# **PART II**

## **BILATERAL BAHA APPLICATION**



# Chapter 6

## **Patient satisfaction with bilateral bone anchored hearing aids - The Birmingham experience**

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David W Proops

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## Abstract

The Birmingham Bone Anchored Hearing Aid (BAHA) programme has fitted more than 300 patients with unilateral bone anchored aids since 1988. Some of the patients who benefited well with unilateral aids and who had used bilateral conventional aids previously applied for bilateral amplification. To date fifteen patients have been fitted with bilateral BAHAs. The benefits of bilateral amplification have been compared to unilateral amplification in 11 of these patients. Subjective analysis in the form of validated comprehensive questionnaires was undertaken.

The Glasgow Benefit Inventory (GBI), which is a subjective patient orientated post-interventional questionnaire developed to evaluate any otorhinolaryngological surgery and therapy was administered. The results revealed that the use of bilateral bone-anchored hearing aids significantly enhanced general well being (patient benefit) and improved the patient's state of health (quality of life). The Chung and Stephens questionnaire which addresses specific issues related to binaural hearing was used. Our preliminary results are encouraging and are comparable to the experience of the Nijmegen BAHA group.

## Introduction

The Birmingham BAHA programme since 1988 has implanted both paediatric and adult patients. An evaluation of patient satisfaction and quality of life after BAHA implantation was undertaken.<sup>1,3</sup> In addition to a high degree of patient satisfaction, a significant improvement in the quality of life has been reported amongst BAHA users. Recently, some of the patients who had previous experience with binaural hearing applied for a second side BAHA. Encouraged by the experience of the Nijmegen BAHA group,<sup>4,6</sup> the Bilateral BAHA Implantation programme was started in Birmingham in 1995. The practice of bilateral prescription of conventional hearing aids in the United Kingdom is variable and in most centres unsatisfactory.<sup>7</sup> Financial constraints on the National Health Service (NHS) and perhaps ignorance of benefit account for the poor practice of bilateral fitting.<sup>7</sup>

15 patients have been implanted with a second side BAHA to date. In this pilot study, 11 of these patients who had used their second side BAHA for longer than 12 months have been evaluated. Patient benefit and specific issues of binaural hearing have been studied.

## Patients and Methods

Since 1995, 15 patients have received a second side BAHA. The criteria that were used in selecting these patients were as follows:

- 1 Bilaterally symmetrical hearing loss

(interaural threshold difference of less than 15 dB four-tone-average).

2. Previous knowledge and experience with binaural hearing (conventionally aided bilaterally or unaided).
3. Professional needs of the users: all the patients that have been implanted are in professions that would require the benefits of binaural hearing, e.g., businessmen, teachers and nurses.
4. Motivation - all the patients voluntarily applied for a second side BAHA.
5. Age - the bilateral implant programme has not been extended to the paediatric (under 18 years) population as yet.

12 of these patients who had used their bilateral BAHAs for longer than 12 months were included in the evaluation (Table 1). The 12-month-period was to allow acclimatisation with the bilateral aids and obviate any bias due to initial enthusiasm. The subjective evaluation strategy included two postal questionnaires that were previously validated.

Table 1. Age and sex distribution with diagnosis and duration of BAHA use

Patient number	Age (in years)	Gender	Diagnosis	I BAHA	II BAHA
P.1	31	F	Treacher Collins syndrome	10 years	5 years
P.2	53	M	Bilateral mastoid cavities	10 years	3 years
P.3	31	F	Bilateral congenital hearing loss	4 years	3 years
P.4	22	F	Treacher Collins syndrome	10 years	30 months
P.5	54	F	Bilateral chronic otitis media	5 years	30 months
P.6	42	M	Bilateral mastoid cavities	12 years	2 years
P.7	39	M	Goldenhar's syndrome	4 years	2 years
P.8	45	F	Bilateral microtia	4 years	2 years
P.9	48	F	Bilateral chronic otitis media	3 years	18 months
P.10	42	F	Bilateral acquired otosclerosis	4 years	16 months
P.11	47	F	Bilateral chronic otitis media	5 years	12 months
P.12	53	F	Bilateral mastoid cavities	5 years	12 months

Table 2 Example of questions used in the modified Glasgow Benefit Inventory questionnaire

*Since you received your second BAHA, have you found it easier or harder to deal with company?*

- |               |           |
|---------------|-----------|
| A Much harder | (score 1) |
| B Harder      | (score 2) |
| C No change   | (score 3) |
| D Easier      | (score 4) |
| E Much easier | (score 5) |

The Glasgow Benefit Inventory (GBI) questionnaire was sent to each patient. This tool was described by Robinson *et al* in 1996 and consists of 18 questions (Appendix 1).<sup>8</sup> Two additions were made to our questionnaire: Four questions relating to the success of the BAHA (Appendix 2) and a 10 cm linear analogue scale reflecting state of health before and after first BAHA and the second BAHA (Appendix 3). Neither of these modifications was described in the original GBI strategy. All the questions in this modified questionnaire were based on a five point Likert scale. An example of the questions and the scoring system has been described in Table 2. Score 1 is a poor satisfaction score and score 5 reflects highest satisfaction. BAHA users were advised to complete separate questionnaires for their first BAHA and their second BAHA.

The Chung and Stephens Binaural Hearing Aid questionnaire was proposed to determine how certain audiological, physical and social factors influence the use of bilateral hearing aids.<sup>9</sup> Selected questions from the four sections of this questionnaire were used with the study group (Appendix 4). Specific issues addressing binaural hearing were studied.

No analytical statistical package has been applied to the results as the number of patients in the study group is small (n=11) and would make the power of such analysis insignificant. However descriptive data in the form of bar charts, cumulative scores and percentages are presented.

## Results

15 patients have been implanted with bilateral BAHA to date. 12 of the patients had used their second BAHA for 12 months or longer (Table 1). One of these patients (p.10) did not choose to answer the questionnaires or attend the audiological evaluation for personal reasons. However, it was learnt during a clinic visit that the patient used her second BAHA for special situations only that included social gatherings and supermarkets.



Of the 12 patients, 6 had chronic suppurative otitis media or discharging mastoid cavities. 4 of them reported dry ears following BAHA use in both ears and 2 reported occasional otorrhoea. 2 patients suffered from Treacher Collins syndrome, one from Goldenhar's syndrome and one other patient had bilateral nonsyndromic microtia. All four benefited with bilateral BAHA and bilateral bone-anchored auricular prostheses, implanted at various stages. One patient suffered from congenital bilateral conductive loss, perhaps congenital otosclerosis and another patient had features strongly suggestive of bilateral acquired otosclerosis. Both these patients chose the option of bilateral BAHA.

### ***Glasgow Benefit Inventory***

The original GBI questionnaire with its eighteen questions and the additional four questions from our group consisted of five-answer options (five-point Likert scale) ranging from a large change for the worse to a large change for the better (Table 2).

The question on success of their bone anchored hearing aids received an interesting response, the second BAHA being more successful than the first (Figure 1). More patients were pleased with the second BAHA (10 patients scored 5, greatly or moderately pleased) than they were with the first (6 patients scored 5). Members of the family of most patients believed that the second BAHA was more successful than the first implant. All eleven patients agreed that they would encourage others with a similar condition to wear bilateral bone anchored hearing aids.

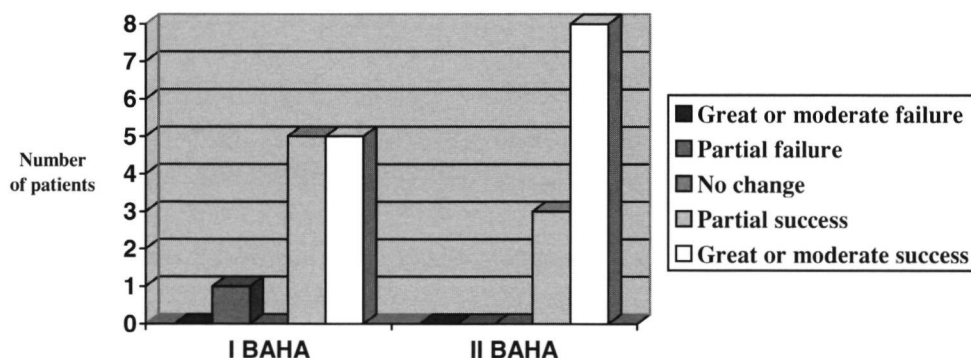


Figure 1. How successful do you think your BAHA is?

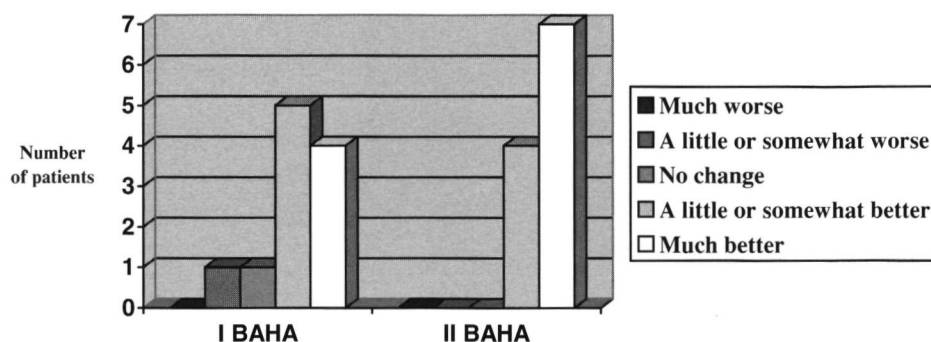


Figure 2. Has getting a BAHA made your overall life better or worse?

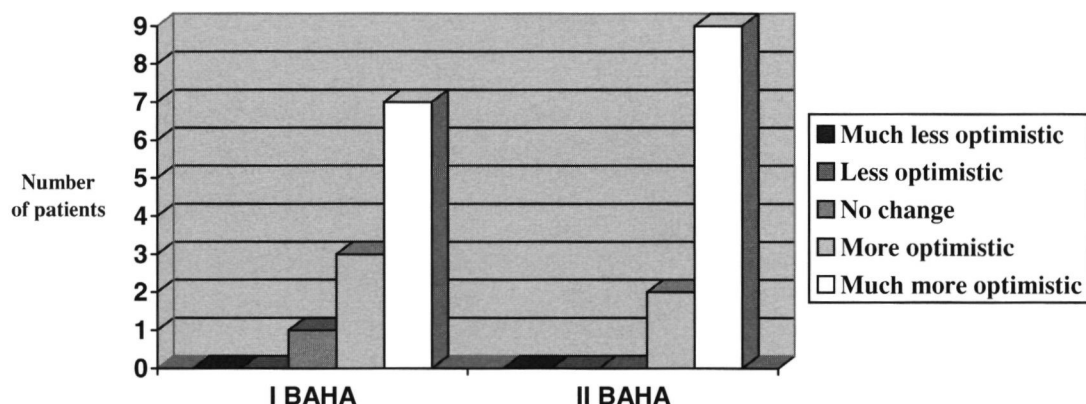


Figure 3. Since you received your BAHA, have you felt MORE or LESS optimistic about the future?

Most patients believed the second BAHA made a remarkable difference to the things they did, made their overall lives much better and hence felt more optimistic about their futures (Figures 2 and 3). There was little embarrassment with the first aid and none with the second and the second BAHA was a great self-confidence booster (Figure 4). Most BAHA users found it easier to deal with company with two implants than with the one (Figure 5). Equivocal responses were obtained to the questions on support from friends and visits to the family doctor (questions g and h, GBI, appendix 1). The majority of them were confident of better job opportunities with bilateral aids than with unilateral aids (Figure 6). Questions on self-consciousness and 'number of people that care' received equivocal responses (questions j and k, GBI).

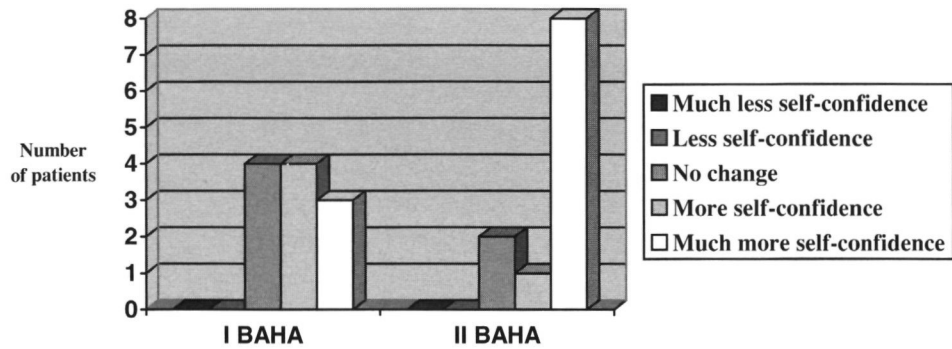


Figure 4. Since getting the BAHA, do you have MORE or LESS self-confidence?

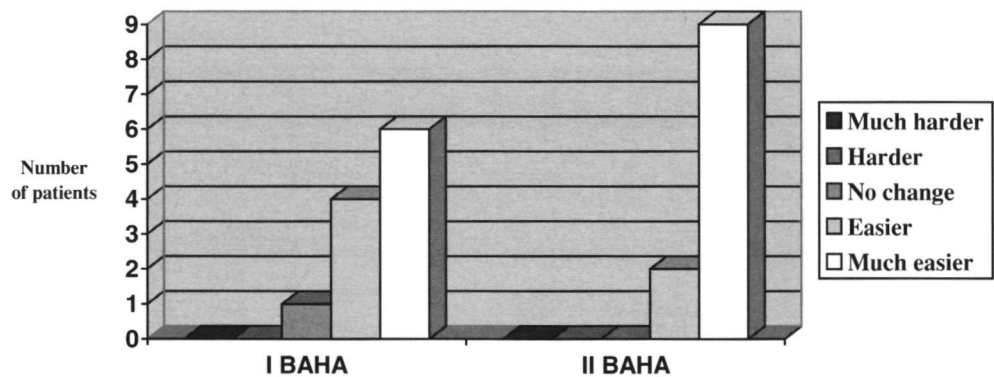


Figure 5. Since you received your BAHA, have you found it easier or harder to deal with company?

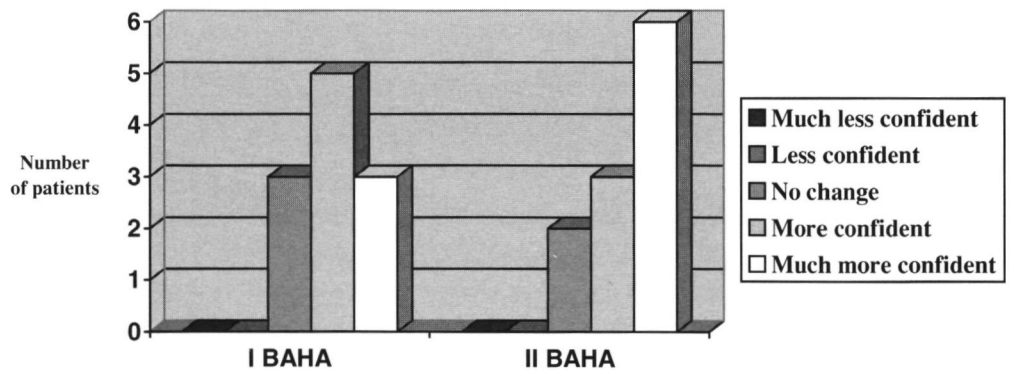


Figure 6. Since you received your BAHA, do you feel MORE or LESS confident about job opportunities?

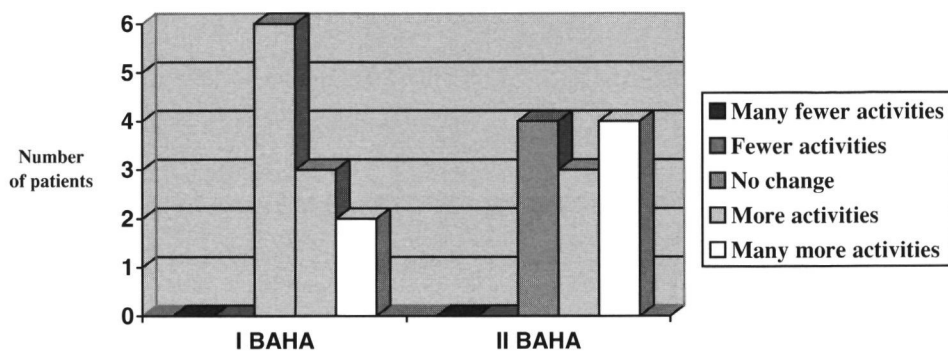


Figure 7. Since getting the BAHA, do you participate in more or fewer social activities?

Table 3. State of health before and after FIRST and SECOND BAHA implants

Patient number	Before BAHA	After FIRST BAHA	After SECOND BAHA
p.1	80	80	85
p.2	35	70	80
p.3	70	88	100
p.4	50	70	80
p.5	60	80	85
p.6	25	85	85
p.7	80	90	90
p.8	80	90	94
p.9	63	80	90
p.10	-	-	-
p.11	48	83	98
p.12	65	80	90

However, it was interesting to note that all six patients with discharging ears reported dry ears or less discharge with bilateral BAHAs than unilateral and hence minimised the need for medications in the form of ear drops and antibiotics (questions l and m, GBI).

The majority of them felt better about themselves (10 scoring 5 with second BAHA compared to 6 with the first), received better support from family members (7 scoring 5 with two BAHAs compared to 4 with one) and were less inconvenienced by their hearing problem (11 scoring 5 with two aids compared to 6 with one) with bilateral BAHA implants (questions n, o and p, GBI). And finally, most of the BAHA users were able to take part in social activities to a greater extent with both BAHAs than they could with one BAHA (Figure 7).

### ***Visual Analogue Scale***

The ten centimetre linear analogue scale was introduced as a modification in the GBI questionnaire to directly address the state of health both before and after obtaining the first and then the second bone anchored hearing aid (Appendix 3). Improvement in the state of health of the patients following the use of a bone anchored hearing aid was observed to be significant with the first BAHA and this was even better with the second (Table 3).

### ***Chung and Stephens questionnaire***

Selected questions from the original Chung and Stephens questionnaire were administered to the bilateral BAHA users (Appendix 4). All the eleven patients were very satisfied with the two BAHAs. 7 of them used the two aids all the time and 4 used them most of the time (questions 1 and 2, Appendix 4). All of them used the two aids for 8 to 12 hours or more everyday and seven days a week (questions 3 and 4). For speech in quiet situations involving 1 or 2 persons, 8 of them preferred two aids to one and two of them did not perceive any difference with one or two aids (Figure 8). Listening to radio, television and records necessitated the use of two BAHAs as did attending meetings, church, pictures or the theatre (Figures 9 and 11). For listening in noisy surroundings, 8 of the BAHA users switched on both aids compared to 3 using one aid only (Figure 10). The majority of them used both the aids for listening to conversation from a distance of 20 feet or more (Figure 12). 9 of them utilised inputs from both the BAHA implants for localisation of sounds whilst two patients did not find any difference with one or two aids (Figure 13). Most of them were comfortable and more relaxed using both the bone anchored aids than one most of the time (Figure 14).

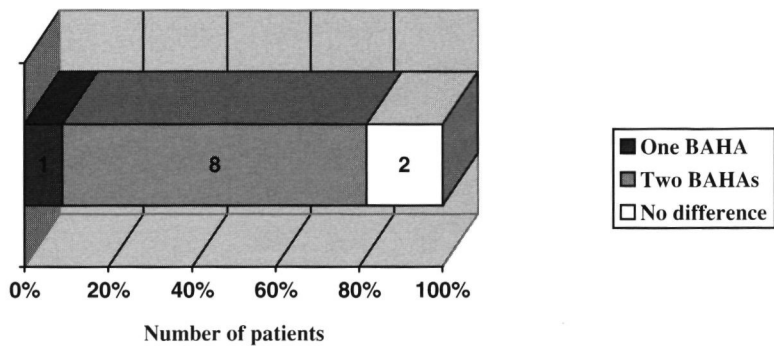


Figure 8. Speech in quiet situations involving 1 or 2 persons

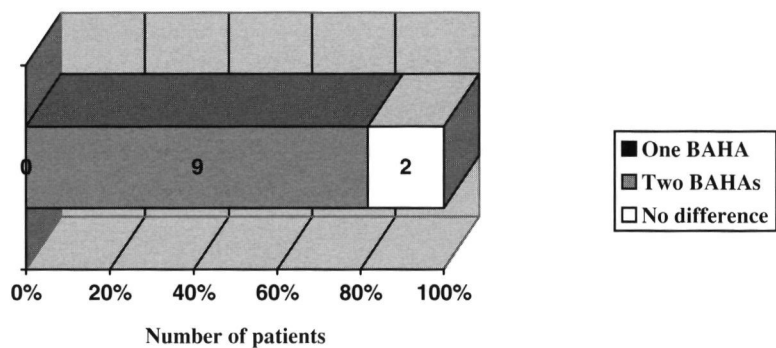


Figure 9. Listening to Radio, Television or Records

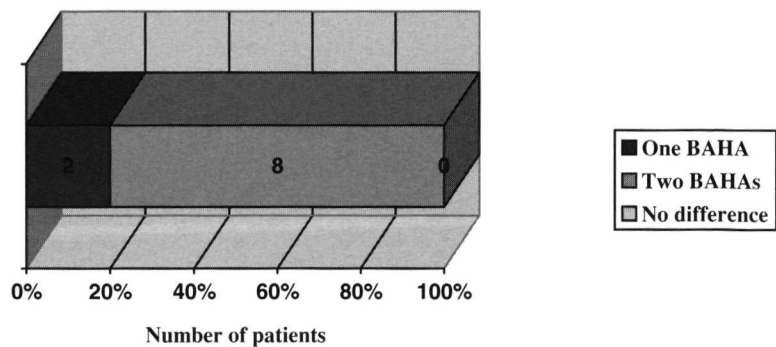


Figure 10. Speech in noisy situations

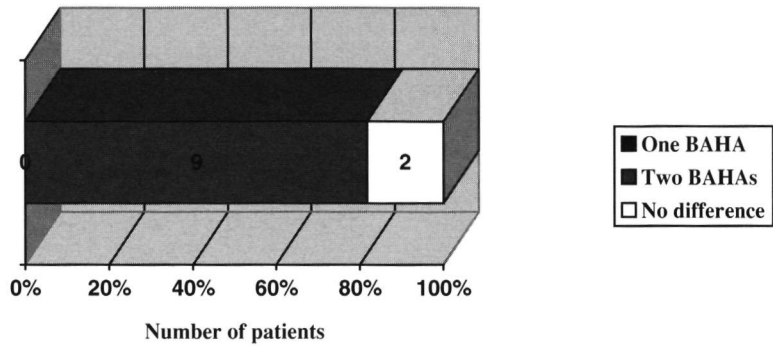


Figure 11. Meetings, Church, Pictures and Theatre

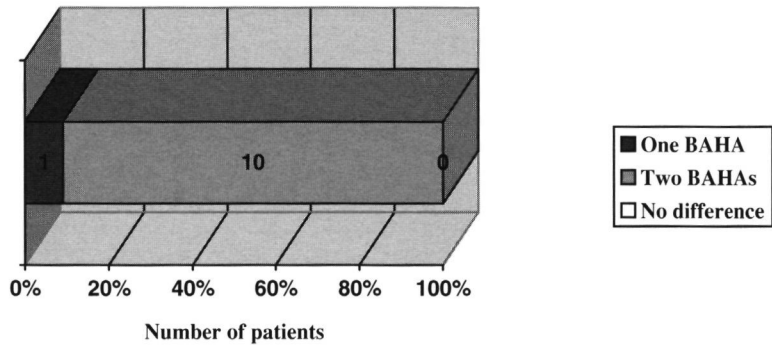


Figure 12. Listening to conversation from a distance (over 20 feet)

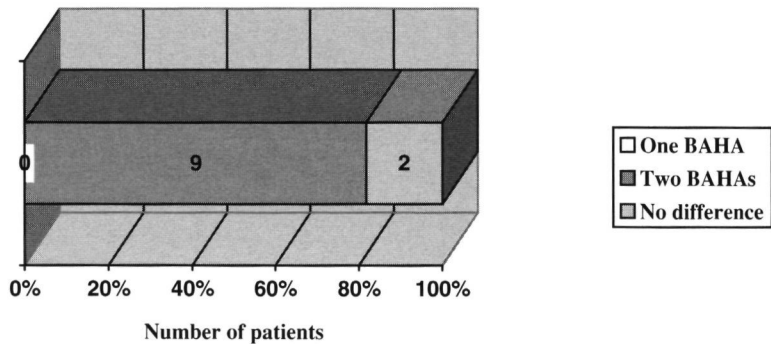


Figure 13. Localisation of sounds

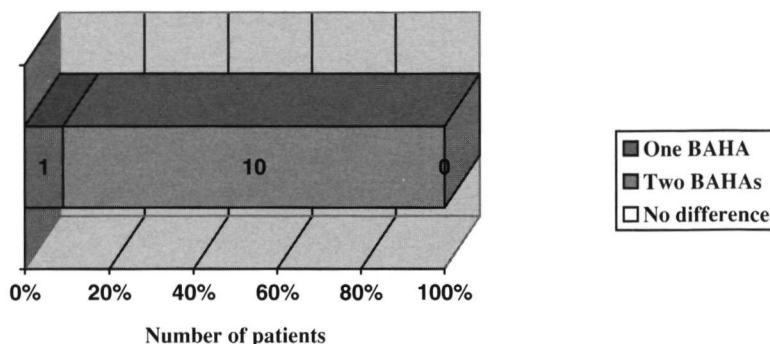


Figure 14. When listening, are you more comfortable (more relaxed) with one or two BAHAs?

## Discussion

Binaural hearing may be considered as important to an individual as binocular vision.<sup>7</sup> Bilateral fitting of hearing aids is a practice that appears to be dictated by the knowledge, attitudes of local otolaryngology and audiology teams and most certainly by cost issues.<sup>7</sup> It has been demonstrated that there is improved sound localisation ability and better speech-in-noise perception with bilateral air conduction aids.<sup>10,11</sup> However, binaural hearing with bone conduction is a subject of controversy as it is well known that sound amplification by bone conduction stimulates both the cochleae. It has been clearly shown by Stenfelt *et al* that interaural attenuation of bone conducted sounds may vary between -15 and +40 decibels and in the lower frequencies, stimulation via bone conduction may result in higher stimulus levels at the contralateral cochlea.<sup>12</sup> Many patients with symmetrical hearing loss prefer bilateral amplification to unilateral amplification when fitted with the air-conduction hearing aids. Bilateral amplification may be successful in restoring binaural hearing depending on the hearing configuration and the integrity of the peripheral auditory system.<sup>13</sup>

In the Netherlands, the majority of bone conduction hearing aids is prescribed bilaterally with transducers incorporated in the bows of eyeglasses.<sup>13</sup> The Nijmegen BAHA team has been the first group to evaluate the benefits of bilateral BAHA. The authors have clearly shown that bilateral fitting of BAHA produces binaural hearing.<sup>4-6,13</sup> The Gothenburg BAHA group has implanted 12 patients with bilateral BAHA and these patients are presently being evaluated (Anders Tjellstrom, personal communication, 2001).



The Birmingham BAHA group started bilateral implantation in 1995. The preliminary results of the case series were presented at the British Academic Conference in Otolaryngology, Cambridge, 1999<sup>14</sup>. Encouraged by our initial results and the Nijmegen experience, more patients are being implanted with bilateral BAHA. The first 11 of the bilateral BAHA users underwent both subjective and objective evaluation<sup>15</sup>.

The Glasgow Benefit Inventory questionnaire is a patient orientated questionnaire and consists of eighteen post-intervention questions (Appendix 1). It provides a measure of patient benefit from ENT procedures. The GBI allows a comparison of benefit across different therapeutic or surgical interventions and is designed to measure change in health status. Health status is defined as the general perception of well-being that includes total physical, social and psychological well-being<sup>8</sup>. Our study included four additional questions and a linear analogue scale of health status (Appendix 2 and 3). In response to the questions from the GBI and its modifications, all eleven patients who responded believed that the second BAHA was a greater success than the first (Figures 1 to 7).

Chung and Stephens in 1986, produced the results of their questionnaire survey on two hundred patients fitted with bilateral hearing aids<sup>9</sup>. The questionnaire was divided into four sections and addressed patient satisfaction and the amount of use of their bilateral hearing aid fitting (Section A), mode of amplification for listening under various situations (Section B), patients' ability to localise sounds (Section C) and finally, problems encountered in using two hearing aids (Section D). Some of the questions from this questionnaire were used in our study on bilateral BAHAs (Appendix 4). The majority of the patients used both aids for specific situations as illustrated in Figures 8 to 14. It was interesting to note that patients who had used the second BAHA for less than two years appeared to perceive no difference with the use of one or two BAHAs in some of these situations. A gradual process of perceptual acclimatisation was acknowledged by patients who had used both their BAHAs for longer periods. In general, a high degree of patient satisfaction with bilateral BAHAs was reported comparable to the Nijmegen studies.

## **Conclusions**

Eleven patients who had used bilateral bone anchored hearing aids reported a high degree of satisfaction with the two aids with respect to speech perception in quiet, speech recognition in noise and localisation of sounds. A greater improvement in the state of health and hence quality of life was perceived with bilateral BAHAs than with unilateral BAHA.

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**Appendix 1:**


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**The Glasgow Benefit Inventory (GBI) Questionnaire**

***This questionnaire asks how things have changed since you received your second BAHA***

- a) Has getting the *second BAHA* affected the things you do?
  - Option 1 Much worse
  - Option 2 A little or somewhat worse
  - Option 3 No change
  - Option 4 A little or somewhat better
  - Option 5 Much better
- b) Has getting the *second BAHA* made your overall life better or worse?
  - Option 1 Much better
  - Option 2 A little or somewhat better
  - Option 3 No change
  - Option 4 A little or somewhat worse
  - Option 5 Much worse
- c) Since you received your *second BAHA*, have you felt more or less optimistic about the future?
  - Option 1 Much more optimistic
  - Option 2 More optimistic
  - Option 3 No change
  - Option 4 Less optimistic
  - Option 5 Much less optimistic
- d) Since you received your *second BAHA*, do you feel more or less embarrassed with a group of people?
  - Option 1 Much more embarrassed
  - Option 2 More embarrassed
  - Option 3 No change
  - Option 4 Less embarrassed
  - Option 5 Much less embarrassed
- e) Since you received your *second BAHA*, do you have more or less self-confidence?
  - Option 1 Much more self-confidence
  - Option 2 More self-confidence
  - Option 3 No change
  - Option 4 Less self-confidence
  - Option 5 Much less self-confidence
- f) Since you received your *second BAHA*, have you found it easier or harder to deal with company?
  - Option 1 Much easier
  - Option 2 Easier
  - Option 3 No change
  - Option 4 Harder
  - Option 5 Much harder

- g) With your *second BAHA*, do you feel that you have more or less support from your friends?  
Option 1 Much more support  
Option 2 More support  
Option 3 No change  
Option 4 Less support  
Option 5 Much less support
- h) With your *second BAHA*, have you been to your family doctor for any reason, more or less often?  
Option 1 Much more often  
Option 2 More often  
Option 3 No change  
Option 4 Less often  
Option 5 Much less often
- i) Since you received your *second BAHA*, do you feel more or less confident about job opportunities?  
Option 1 Much more confident  
Option 2 More confident  
Option 3 No change  
Option 4 Less confident  
Option 5 Much less confident
- j) Since you received your *second BAHA*, do you feel more or less self-conscious?  
Option 1 Much more self-conscious  
Option 2 More self-conscious  
Option 3 No change  
Option 4 Less self-conscious  
Option 5 Much less self-conscious
- k) Since you received your *second BAHA*, are there more or fewer people who really care about you?  
Option 1 Many more people  
Option 2 More people  
Option 3 No change  
Option 4 Fewer people  
Option 5 Much fewer people
- l) Since you received your *second BAHA*, do you catch colds or infections more or less often?  
Option 1 Much more often  
Option 2 More often  
Option 3 No change  
Option 4 Less often  
Option 5 Much less often
- m) Since you received your *second BAHA*, have you had to take more or less medicine for any reason?  
Option 1 Much more medicine  
Option 2 More medicine  
Option 3 No change  
Option 4 Less medicine  
Option 5 Much less medicine

- n) Since you received your *second BAHA*, do you feel better or worse about yourself?
- Option 1 Much better
  - Option 2 Better
  - Option 3 No change
  - Option 4 Worse
  - Option 5 Much worse
- o) Since your *second BAHA*, do you feel that you have more or less support from your family?
- Option 1 Much more support
  - Option 2 More support
  - Option 3 No change
  - Option 4 Less support
  - Option 5 Much less support
- p) Since your *second BAHA*, are you more or less inconvenienced by your hearing problem?
- Option 1 Much more inconvenienced
  - Option 2 More inconvenienced
  - Option 3 No change
  - Option 4 Less inconvenienced
  - Option 5 Much less inconvenienced
- q) Since your *second BAHA*, have you been able to participate in more or fewer social activities?
- Option 1 Many more activities
  - Option 2 More activities
  - Option 3 No change
  - Option 4 Fewer activities
  - Option 5 Many fewer activities
- r) Since your *second BAHA*, have you been more or less inclined to withdraw from social situations?
- Option 1 Much more inclined
  - Option 2 More inclined
  - Option 3 No change
  - Option 4 Less inclined
  - Option 5 Much less inclined

## Appendix 2:

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### Modifications: Subjective opinions regarding success of BAHA

- a) How successful do you think your *second BAHA* is?
    - Option 1 Great or moderate failure/1
    - Option 2 Partial failure/2
    - Option 3 No change/3
    - Option 4 Partial success/4
    - Option 5 Great or moderate success/5
  
  - b) Do you feel pleased or disappointed about getting a *second BAHA*?
    - Option 1 Greatly or moderately pleased/5
    - Option 2 A little or somewhat pleased/4
    - Option 3 No change/3
    - Option 4 A little or somewhat disappointed/2
    - Option 5 Greatly or moderately disappointed/1
  
  - c) How successful do members of your family and close friends think your *second BAHA* is?
    - Option 1 Great or moderate success/1
    - Option 2 Partial success/2
    - Option 3 No change/3
    - Option 4 Partial failure/2
    - Option 5 Great or moderate failure/1
  
  - d) If you knew that someone else in your family or a close friend had a similar condition to yours, would you encourage them to get a similar *second BAHA*?
    - Option 1 Definitely not/1
    - Option 2 Probably not/2
    - Option 3 Can't decide/3
    - Option 4 Probably yes/4
    - Option 5 Definitely yes/5
-

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**Appendix 3:**


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**Modification : State of health before and after BAHA**

We would like you to indicate your state of health. To help you, we would like you to imagine a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Think about how your health affects:

- Your general well-being
- Your independence and ability to take care of yourself
- Your ability to take care of others
- How you feel about yourself
- Your ability to get around and communicate
- Your ability to socialise
- Your performance at work

**YOUR STATE OF HEALTH TODAY WITH YOUR *SECOND* BAHA**

We would like you to choose a point on the scale that indicates how good or bad you consider your state of health is today with your BAHA

Worst-----Best

**YOUR STATE OF HEALTH WITH YOUR *FIRST* BAHA**

Worst-----Best

**YOUR STATE OF HEALTH *BEFORE* YOU RECEIVED YOUR *FIRST* BAHA**

Worst-----Best

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**Appendix 4:**

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**Chung and Stephens questionnaire (Modified)**

- 1 Are your present hearing aids
  - a very satisfactory
  - b satisfactory
  - c unsatisfactory
  - d very unsatisfactory
- 2 Do you wear two hearing aids
  - a all the time
  - b most of the time
  - c often (for some time everyday)
  - d never
- 3 On average, how many hours a day do you use two hearing aids?
  - a 0
  - b less than 1
  - c 1-4
  - d 4-8
  - e 8-12
  - f over 12
- 4 On average, how many days a week do you use two hearing aids?
  - a 0    e 4
  - b 1    f 5
  - c 2    g 6
  - d 3    h 7
- 5 When you are listening to speech in quiet situations involving 1 or 2 persons, do you find listening easier using
  - a 1 hearing aid
  - b 2 hearing aids
  - c no difference
- 6 When you are listening to TV, radio or records, do you find listening easier using
  - a 1 hearing aid
  - b 2 hearing aids
  - c no difference
- 7 When you are listening to speech in noisy situations, do you find listening easier using
  - a 1 hearing aid
  - b 2 hearing aids
  - c no difference

8. When you are at a meeting, church, pictures or theatre, do you find listening easier using:

- a. 1 hearing aid
- b. 2 hearing aids
- c. no difference

9. When you are listening to conversation from a distance (over 20 feet), do you find listening easier using:

- a. 1 hearing aid
- b. 2 hearing aids
- c. no difference

10. When you have to locate sounds, do you find listening easier using:

- a. 1 hearing aid
- b. 2 hearing aids
- c. no difference

11. When you are listening, do you find it more comfortable (more relaxed and easier) using:

- a. 1 hearing aid
  - b. 2 hearing aids
  - c. no difference
-



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# Chapter 7

## **Speech intelligibility with bilateral bone anchored hearing aids - The Birmingham experience**

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**Abstract**

The Birmingham bone anchored hearing aid (BAHA) programme, since its inception in 1988, has fitted more than 300 patients with unilateral bone anchored hearing aids. Recently some of the patients who benefited extremely well with unilateral aids applied for bilateral amplification. To date 15 patients have been fitted with bilateral BAHAs. The benefits of bilateral amplification have been compared to unilateral amplification in 11 of these patients who have used their second BAHA for 12 months or longer. Following a subjective analysis in the form of comprehensive questionnaires, objective testing was undertaken to assess specific issues such as speech recognition in quiet, speech recognition in noise and a modified speech-in- simulated-party-noise (Plomp) test.

Speech in quiet testing revealed 100% score with both unilateral and bilateral BAHAs. With speech in noise all 11 patients scored marginally better with bilateral aids compared to best unilateral responses. The modified Plomp test demonstrated that bilateral BAHAs provided maximum flexibility when the origin of noise cannot be controlled as in day-to-day situations. In this small case series the results are positive and are comparable to the experience of the Nijmegen BAHA group.

**Introduction**

351 patients have been implanted with bone anchored hearing aids (BAHA) on the Birmingham BAHA programme since 1988. These include both adults and children. In addition to a high degree of patient satisfaction, a significant improvement in the quality of life has been reported amongst BAHA users. Encouraged by the experience of the Nijmegen BAHA group, the Bilateral BAHA Implantation programme was started in 1995. A number of patients who had used bilateral conventional aids previously and whose professional needs warranted good binaural hearing, applied for a second side BAHA. Financial constraints and perhaps ignorance of benefit account for the poor practice of bilateral fitting on the NHS in the United Kingdom.<sup>1</sup>

15 patients have been implanted with a second side BAHA on the bilateral BAHA programme. In this study, 11 of these patients who had used their second side BAHA for longer than 12 months have been evaluated objectively. Speech recognition in quiet, in noise and the results of the modified Plomp test are presented.

**Patients and Methods**

A total of 15 patients have been implanted with bilateral BAHAs in Birmingham. To avoid enthusiasm bias and to allow acclimatisation with the use of the second BAHA, 12 patients

who had used both their BAHAs for 12 months or more were invited to participate in this study on the benefits of bilateral BAHA implantation. Table 1 provides detailed information of the study group that includes 9 females and 3 males.

Although not stringent, certain selection criteria were used as follows:

1. Previous knowledge and experience with binaural hearing (conventionally aided or unaided).
2. Bilaterally symmetrical hearing loss  
(interaural threshold difference of less than 15 dB four-tone-average).
3. Professional needs of the users: e.g., businessmen, teachers and nurses.
4. Motivation -patients voluntarily applied for a second side BAHA.
5. Age - the bilateral implantation facility has not been extended to children yet.

Following a postal questionnaire study<sup>2</sup> on patient benefit and quality of life using the two BAHAs, the study group was invited to attend the audiology service for objective evaluation of patient benefit.

Table 1. Age and sex distribution with diagnosis and duration of BAHA use

Patient Number	Age (in years)	Gender	Diagnosis	I BAHA	II BAHA
P.1	31	F	Treacher Collins syndrome	10 years	5 years
P.2	53	M	Bilateral mastoid cavities	10 years	3 years
P.3	31	F	Bilateral congenital hearing loss	4 years	3 years
P.4	22	F	Treacher Collins syndrome	10 years	30 months
P.5	54	F	Bilateral chronic otitis media	5 years	30 months
P.6	42	M	Bilateral mastoid cavities	12 years	2 years
P.7	39	M	Goldenhar's syndrome	4 years	2 years
P.8	45	F	Bilateral microtia	4 years	2 years
P.9	48	F	Bilateral chronic otitis media	3 years	18 months
P.10	42	F	Bilateral acquired otosclerosis	4 years	16 months
P.11	47	F	Bilateral chronic otitis media	5 years	12 months
P.12	53	F	Bilateral mastoid cavities	5 years	12 months

Table 2. Audiological evaluation of bone anchored hearing

1 Unaided Thresholds	Soundfield Levels - dB A
2. Aided Thresholds	Right BAHA Left BAHA Bilateral BAHA
3. Soundfield Speech with Arthur-Boothroyd (AB) Word Lists	Right BAHA Left BAHA Bilateral BAHA
4 Bamford-Koval-Bench (BKB) Sentences a) In Quiet b) In Noise - Signal to Noise Ratios Plus 10 dB Zero dB Minus 10 dB	Right BAHA Left BAHA Bilateral BAHA
5. Modified Plomp Multitalker Noise Test a) Sound Front Noise Front (SFNF) b) Sound Front Noise Left (SFNL) c) Sound Front Noise Right (SFNR)	Right BAHA Left BAHA Bilateral BAHA

The objective audiological evaluation (Table 2) included unaided soundfield levels (dB A) and aided thresholds with right, left and bilateral BAHAs. Soundfield speech using the Arthur-Boothroyd (A-B) word lists was evaluated with right, left and bilateral aided situations.<sup>3</sup>

For the evaluation of speech-in-quiet and speech-in-noise, Bamford-Koval-Bench (BKB) sentences were used.<sup>4</sup> This included the evaluation of the three individual situations, i.e., right, left and bilateral aiding, at signal-to-noise ratios (SNR) of plus 10 dB, 0 dB and minus 10 dB.

A modification of the Plomp multitalker noise test was used to evaluate speech-in-noise with open-set speech recognition.<sup>5,6,7</sup> The basic test environment is as shown in Figure 1. BKB sentences are presented to patients from Speaker 1 at 70 dBA. Speech babble noise (20 talker/cocktail party noise) is then presented from either speaker, 2 or 3, at a signal to noise ratio of 0 dB. It is then possible to evaluate speech recognition in noise using bilateral, left only and right only BAHA situations. Therefore, there are three basic experimental situations:

1. Sound Front/ Noise Front (SFNF)
2. Sound Front/ Noise Left (SFNL) and
3. Sound Front/ Noise Right (SFNR).

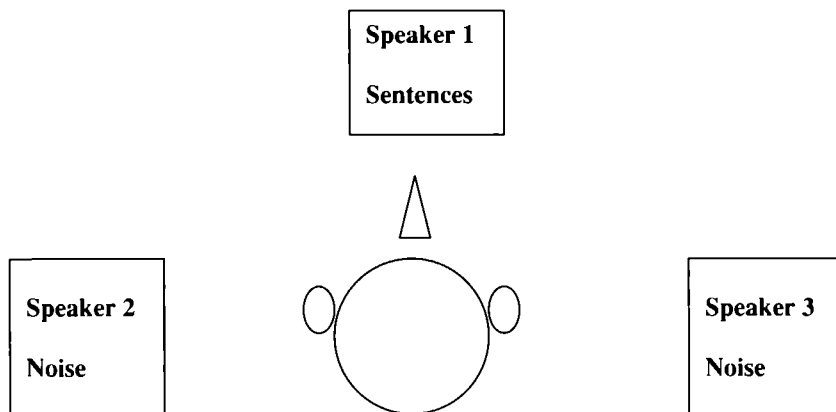


Figure 1. Configuration standard for the modified Plomp speech-in-noise test

No statistical package has been applied to the results as the number of patients in the study group is small ( $n=11$ ) and would make the power of such analysis insignificant. Descriptive data in the form of bar charts, cumulative scores and percentages are presented.

## Results

On the bilateral BAHA programme, 15 patients have received a second side BAHA since 1995. 12 of these patients had used their second BAHA for 12 months or longer (Table 1). Patient 10 did not choose to answer the questionnaires or attend the audiological evaluation for personal reasons. During a clinic visit, it was learnt that the patient used her second BAHA for special situations that included social gatherings and supermarkets.

Age and gender distribution and clinical data of these patients are presented in Table 1. Of the 12 patients, 6 had chronic suppurative otitis media or discharging mastoid cavities. 4 of them reported dry ears following BAHA use in both ears and 2 reported occasional otorrhoea in one or the other ear. The group with congenital bilateral conductive deafness included, 2 patients with Treacher Collins syndrome, one Goldenhar's syndrome, one patient with nonsyndromic bilateral microtia and one with congenital bilateral conductive loss consistent with stapes fixation. Four of these with auricular dysplasia benefited with bilateral BAHA and bilateral bone-anchored auricular prostheses, implanted at different stages. The patient with congenital bilateral conductive loss and another patient who had features strongly suggestive of bilateral acquired otosclerosis chose the third option of bilateral BAHA.<sup>6</sup>

The battery of audiological tests that were performed is listed in Table 2. Unaided thresholds on all eleven patients showed that they satisfied the audiological selection criteria for BAHA implantation and bilateral provision. Aided thresholds were tested with unilateral and bilateral BAHAs. All eleven patients were tested with their volume controls at position 2, which was the position that they used their BAHAs with and was the most comfortable position.

Speech in quiet testing was performed using the BKB sentences. All 11 patients scored 100% scores in all three situations, right, left and bilateral aided conditions. The scores with AB word lists (word lists with 30 words) presented with words at different intensities from 30 dB to 80 dB in a sound field are shown in Figures 2 and 3. The figures clearly demonstrate better scoring with bilateral BAHA compared to the best unilateral response. With speech-recognition in noise, the scores were slightly better with bilateral BAHA compared to the best unilateral BAHA response, either right or left (Figure 4).

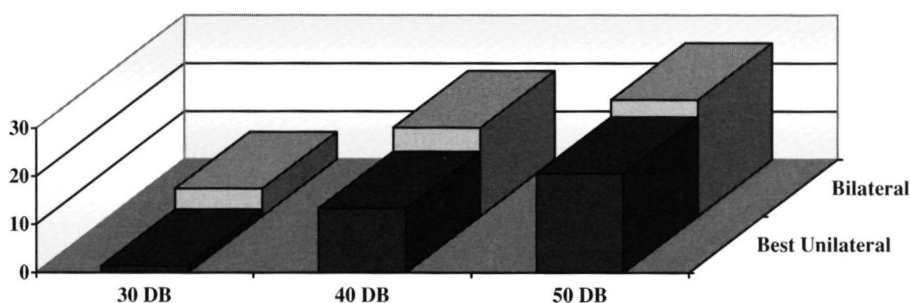


Figure 2. Comparison of best-unilateral BAHA response with bilateral BAHA response: Cumulative A-B word (30 words) list scores at 30 dB, 40 dB and 50 dB intensity levels

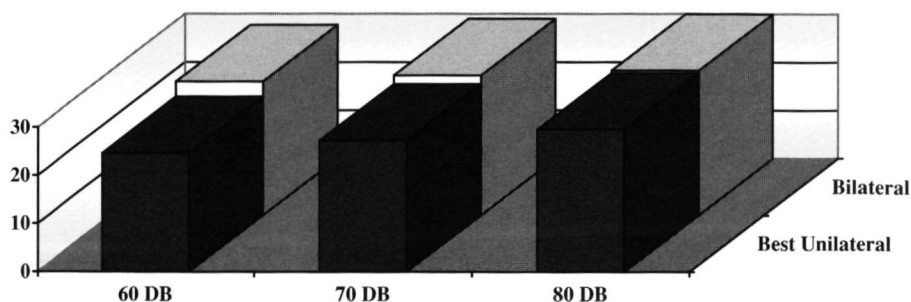


Figure 3. Comparison of best-unilateral BAHA response with bilateral BAHA response: Cumulative A-B word (30 words) list scores at 60 dB, 70 dB and 80 dB intensity levels



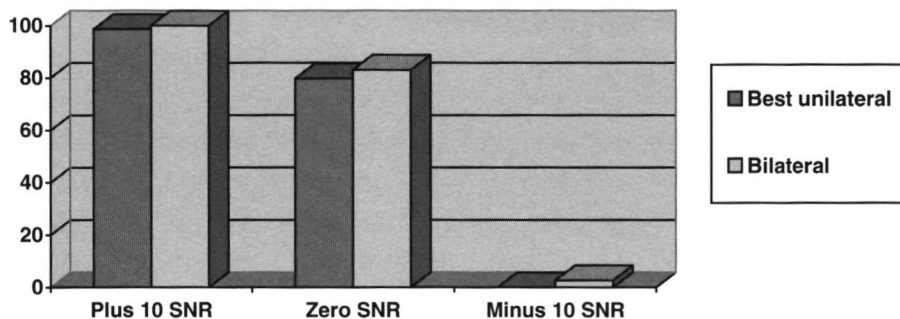


Figure 4. Comparison of best-unilateral BAHA response with bilateral BAHA response: Cumulative BKB sentences scores at plus 10, Zero and minus 10 signal-to-noise ratios

Table 3. Plomp test: Sound Front Noise FRONT (SFNF) situation

Patient Number	Left BAHA only	Right BAHA only	Bilateral BAHAs
P.1	84	80	82
P.2	70	83	90
P.3	63	63	65
P.4	85	85	87
P.5	62	61	65
P.6	76	72	80
P.7	56	58	60
P.8	80	84	97
P.9	83	87	93
P.10	-	-	-
P.11	84	87	91
P.12	93	90	96

Units - percentage correct score The results of the Plomp test are shown in Tables 3, 4 and 5. In the Sound Front/ Noise Front situation, the performance of the BAHA users was equivocal with unilateral or bilateral aids. Some of the candidates obtained better scores with the unilateral situation that they were most familiar with (Table 3). When presenting noise on the same side as the BAHA-in-use (Baffle situation, e.g., noise left for a left only switched-on BAHA), the scores drop dramatically (Tables 4 and 5). This is largely to be expected as the microphone in the aid is positioned to pick up sounds and noise from the specific side better. When noise is presented on the opposite side to the BAHA-in-use (Shadow situation, e.g., noise right for a left only switched-on BAHA), the scores improve dramatically (Tables 4 and 5). In many cases the scores are even better than the bilateral response.

Table 4 Plomp test: Sound Front Noise LEFT (SFNL) situation

Patient Number	Left BAHA only	Right BAHA only	Bilateral BAHAs
P.1	64	<b>87</b>	80
P.2	69	<b>94</b>	78
P.3	3	<b>55</b>	54
P.4	31	<b>85</b>	83
P.5	31	<b>82</b>	44
P.6	27	<b>89</b>	73
P.7	2	<b>76</b>	62
P.8	67	<b>87</b>	95
P.9	71	<b>83</b>	79
P.10	-	-	-
P.11	29	<b>97</b>	58
P.12	47	<b>90</b>	76

Units - percentage correct score

Table 5 Plomp test: Sound Front Noise RIGHT (SFNR) situation

Patient Number	Left BAHA only	Right BAHA only	Bilateral BAHAs
P.1	87	<b>60</b>	80
P.2	97	<b>61</b>	91
P.3	82	<b>13</b>	80
P.4	80	<b>44</b>	85
P.5	72	<b>30</b>	82
P.6	97	<b>19</b>	69
P.7	90	<b>33</b>	71
P.8	79	<b>60</b>	90
P.9	100	<b>88</b>	93
P.10	-	-	-
P.11	91	<b>37</b>	58
P.12	95	<b>59</b>	76

Units - percentage correct score

## Discussion

The benefits of binaural hearing include speech intelligibility, sound localisation and stereophonic appreciation. These effects have been demonstrated in subjects with normal hearing and with those using bilateral conventional air conduction hearing aids.<sup>9-14</sup>

It is well known that sound amplification by bone conduction stimulates both the cochleae. However, Stenfelt *et al* have shown that transcranial attenuation of bone conducted sounds may vary between -15 and +40 decibels.<sup>15</sup> In the lower frequencies, stimulation via bone conduction may result in higher stimulus levels at the contralateral cochlea.<sup>15</sup>

In a cases series involving 25 patients who received bilateral bone anchored hearing aids, Bosman *et al* (Nijmegen group) have unequivocally demonstrated that bilateral amplification restores binaural hearing.<sup>16</sup> However in the United kingdom, bilateral fitting of hearing aids, albeit conventional or bone-anchored, is a practice that appears to be undermined by cost issues and the knowledge and attitudes of local otology teams.<sup>1</sup>

The Nijmegen BAHA team has been the first group to evaluate the benefits of bilateral BAHA. The authors have clearly demonstrated that bilateral fitting of BAHA produces binaural hearing<sup>16 19</sup>. In Nijmegen, the majority of bone conduction hearing aids was prescribed bilaterally with transducers incorporated in the bows of eyeglasses. With demonstration of binaural benefit using bilateral BAHAs, this now has become the treatment of choice in those that satisfy the selection criteria. The Gothenburg BAHA team has implanted 12 patients with bilateral BAHA and the patients are presently being evaluated (Anders Tjellstrom, personal communication, 2001).

In Birmingham, bilateral implantation with BAHA was started in 1995. This was as a result of requests by some of the patients who had appreciated the benefits of binaural hearing previously with conventional aids. The Nijmegen experience with similar patients was encouraging<sup>17 18</sup>.

The first 11 of the bilateral BAHA users underwent both subjective and objective evaluation. The subjective evaluation strategy included two postal questionnaires that were previously validated. This showed a high degree of patient satisfaction and improved quality of life with the second BAHA, compared to the first<sup>2</sup>.

A comprehensive objective strategy has been in practice for evaluation of binaural hearing with conventional hearing aids and BAHAs on the Birmingham Implantation Otology Programme (Table 2). This includes evaluation of unaided thresholds, aided thresholds at optimal volume control and speech recognition tests. Both speech-in-quiet and speech-in-noise tests are evaluated at various levels and signal to noise ratios (SNRs). A modified technique of the Plomp multitalker test is also used. The results presented here are positive. We also propose to undertake annual evaluation of binaural hearing to study the process of perceptual habituation and acclimatisation. A soundfield laboratory is being set up for evaluation of sound localisation with the 12 speaker directional hearing tests. This would enable the team to objectively evaluate the stereophonic benefits of any form of sound amplification including bilateral conventional aids, bilateral BAHAs and bilateral cochlear implants.

## Conclusion

Objective evaluation of patients with bilateral bone anchored hearing aids has revealed improved speech intelligibility with bilateral aiding compared to unilateral aiding. This justifies prescription of bilateral BAHAs to patients who satisfy the selection criteria.

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# **PART III**

## **BILATERAL HEARING AIDS PRESCRIPTION**



# Chapter 8

## **Prescription of Binaural Hearing Aids in the United Kingdom: A Knowledge, Attitude and Practice (KAP) study**

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David W Proops

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## Abstract

The purpose of this questionnaire study was to evaluate the existing knowledge of binaural hearing and the attitudes and practices of prescribing bilateral hearing aids amongst otolaryngologists in the United Kingdom. Of the 950 questionnaires sent to the current members of the British Association of Otolaryngologists and Head and Neck Surgeons (BAO-HNS), there were 591 respondents (62%). The true response rate with completed questionnaires was 59%. 81% of the respondents were aware of the importance of binaural hearing and had a positive attitude towards binaural fitting. The practice of bilateral hearing aid prescriptions was found to be poor amongst all grades on the NHS (less than 10% of all hearing aid prescriptions). This practice in the private sector was variable, dependent largely on patient preference and affordability. The practice of binaural prescription was higher for patients in the paediatric age group than amongst adults. Two common indications for hearing aid prescriptions for unilateral deafness were otitis media with effusion in children (23% of respondents) and for tinnitus masking in adults (12% of respondents). Many otolaryngologists believed that there was not enough evidence to support bilateral bone anchored hearing aid implantation and bilateral cochlear implantation. 94% of the respondents believed that binaural hearing was as important as binocular vision.

## Introduction

Hearing rehabilitation today is a challenge both to the otologist and the audiologist. One is faced with the dilemma of prescribing either hearing aids or offering otologic hearing restoration surgery or more recently, implantation otology. When a decision about hearing aid provision is made, there are more questions to be answered, viz, what aiding strategy to use, one ear or both ears, behind the ear (BTE), in the ear (ITE) or in the canal (ITC) aids, conventional analogue aids or digital aids and so on.

The practice of binaural hearing aid prescription is variable throughout the world. Increased cost is certainly a major deterrent in prescribing binaural aids. There appears to be no consensus opinion regarding guidelines for binaural hearing aid fitting amongst otolaryngologists.

The objectives of this survey questionnaire study were -

- 1 To evaluate the *knowledge* and *attitudes* regarding binaural hearing of otolaryngologists in the UK and
- 2 To evaluate the practice regarding the *prescription* of bilateral hearing aids amongst otolaryngologists in the UK

## Material and Methods

A postal questionnaire survey was undertaken between the months of April and August 2000. The questionnaire was first circulated locally amongst 30 practising otolaryngologists. Their suggestions and modifications were incorporated into the final questionnaire. The revised questionnaire (appendix 1) was sent to all the current members of the British Association of Otolaryngologists and Head and Neck Surgeons (BAO-HNS) in the United Kingdom.

The questionnaire was designed to assess the knowledge, attitude and practice (KAP) of bilateral hearing aids prescription. Both National Health Service (NHS) practice and private practice as regards hearing aids prescription were evaluated.

## Results

A total of 950 questionnaires were sent to all the current members of the British Association of Otolaryngologists and Head and Neck Surgeons. The total number of respondents were 591 i.e. a 62% response rate. Table 1 enumerates the different grades of the respondents. 30 retired consultants returned the questionnaires choosing not to respond to the questions, as they were no longer in practice. The true response rate was therefore 59% (561 correctly completed questionnaires).

Table 1. Distribution of respondents

Grades	Numbers responded
Consultants	373
Retired consultants	47 (30 did not answer questions)
Specialist Registrars	101
Senior House Officers	38
Staff grade surgeons	26
Audiological Physicians	6
Total questionnaires	950
Total respondents	591
Total true respondents	561

### Knowledge

454 (81%) of the respondents were aware of the importance of binaural hearing. Of these, 296 were consultant grade, 132 were training grades and the rest other grades. 70 of these respondents (15%) gave quotes of appropriate literature.<sup>1-5</sup>

206 (37%) were aware of studies that showed benefits with bilateral bone anchored hearing aids (BAHA) (Table 2). 109 (53%) of this group were junior grade and middle grade (staff grade and equivalent) otolaryngologists. 50 of the 206 quoted literature references and 39 of these were junior grades.<sup>6-8</sup>

124 (23%) were aware of studies demonstrating the benefit of bilateral cochlear implants (Table 3). 102 of these (82%) were junior and middle grades. However, only 26 gave appropriate references from literature<sup>9</sup> or from conference presentations and clinical trials and all 26 of these were junior grades.

Table 2. What is your attitude as regards bilateral Bone Anchored Hearing Aids (BAHA) prescription?

Options	No. of respondents (of 561)
I am aware of studies that show benefit	206 (37%)
I do not believe there is sufficient evidence to demonstrate benefit	142 (25%)
I do not believe they work	24 (4%)
I have no opinion	189 (34%)

Table 3. What is your attitude towards bilateral Cochlear Implantation?

Options	No. of respondents (of 561)
I am aware of studies that show benefit	124 (23%)
I do not believe there is sufficient evidence to demonstrate benefit	171 (30%)
I do not believe they work	24 (4%)
I have no opinion	242 (43%)

### Attitude

454 (81%) of the respondents believed in the importance of binaural hearing. 440 (78%) of the otolaryngologists admitted that cost was a limiting factor on the NHS for all types of bilateral hearing aids. However, none of the audiological physicians (6 out of 6) perceived any financial constraints with bilateral hearing aid prescription provision.

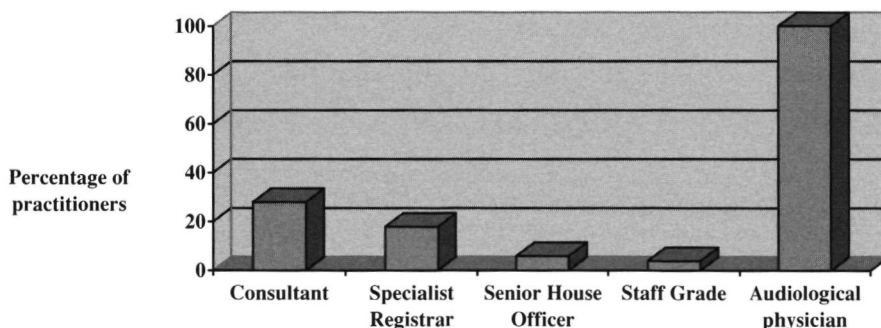
Bilateral bone anchored hearing aids were not popular with the majority of those who were questioned (Table 2). A similar attitude was displayed with regard to bilateral cochlear implantation (Table 3). Amongst retired consultants, 81% had no opinion regarding bilateral BAHAs and 87% had no opinion regarding bilateral cochlear implants. 98% of those respondents, with no opinion as regards bilateral BAHA or cochlear implants, were consultant grade.

An overwhelming 531 respondents (94%) believed that binaural hearing was as important to a patient as binocular vision.

### Practice

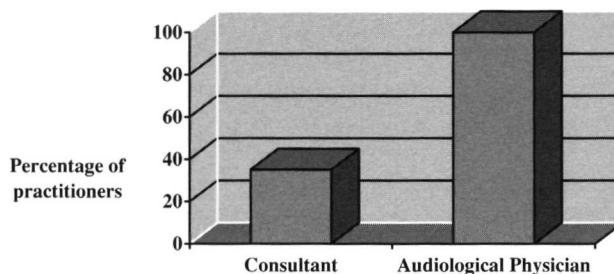
The prescription of bilateral conventional hearing aids on the NHS appears to be poorly practised amongst all grades of otolaryngologists (Figure 1). However, 100% of the small group of audiological physicians that took part in the survey routinely used bilateral hearing aids.

In the private practice sector, the prescription practice was marginally better than on the NHS amongst consultant grades (Figure 2), understandably due to the affordability of additional costs in this sector.



110 (28%) of 390 practising Consultants; 18 (18%) of 101 Specialist Registrars; 3 (6%) of 38 Senior House Officers; 1 (4%) of 26 Staff Grade surgeons; 6 (100%) of 6 Audiological Physicians

Figure 1. Do you prescribe bilateral conventional hearing aids in your NHS practice?



136 (35%) of 390 practising Consultants; 6 (100%) of 6 Audiological Physicians

Figure 2. Do you prescribe bilateral conventional hearing aids in your private-practice?

Table 4. Percentage of hearing aid prescriptions that are bilateral (NHS practice)

Percentage prescriptions	Total number of practitioners
100%	6
90%	3
80%	2
70%	4
60%	4
50%	5
40%	2
30%	5
20%	7
10%	10
Less than 10%	90

138 NHS practitioners prescribing bilateral aids

However, both on the NHS and in the private sector, the majority of the practitioners prescribing bilateral aids (138 of 561 on the NHS and 142 of 396 in the private sector) believed that less than 10% of their prescriptions for hearing aids were for bilateral aids (Tables 4 and 5).

In response to the use of prescribing guidelines for bilateral hearing aids, only 112 (20% of 561) of the respondents had any clinical criteria to aid their management decision. Once again, the 6 audiological physicians interviewed used such audiological criteria. 46% of the respondents stated that they referred such patients requiring bilateral hearing aids to their local audiologists. 96 (17% of 561) stated that routine prescription of bilateral aids occurred in the paediatric population.

Table 5. Percentage of hearing aid prescriptions that are BILATERAL (Private-practice)

Percentage prescriptions	Total number of practitioners
100%	6
90%	9
80%	12
70%	10
60%	8
50%	6
40%	15
30%	18
20%	12
10%	12
Less than 10%	34

142 private practitioners prescribing bilateral aids

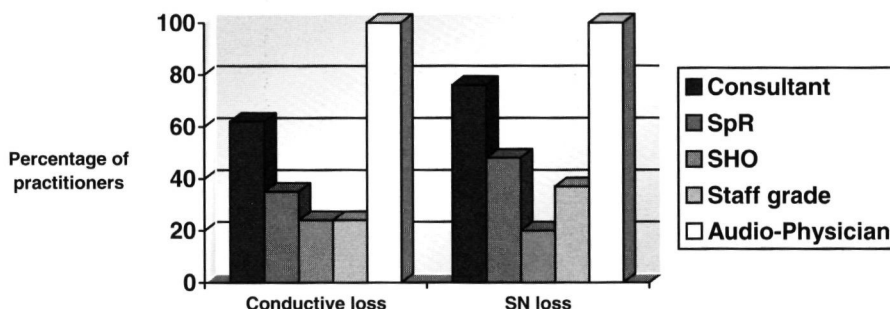


Figure 3. Prescription of hearing aids for unilateral hearing loss

Interestingly, prescription of unilateral hearing aids for both conductive hearing loss and sensorineural loss appeared to be a practised procedure. This was reflected amongst all grades of NHS practitioners (Figure 3). Otitis media with effusion in children was quoted as a common indication for conductive loss (129 of 561 respondents). In the sensorineural group, unilateral hearing aids were prescribed more as tinnitus maskers than aids to hearing (67 of 561 respondents).

## Discussion

Hearing aid prescription is perhaps one of the commonest therapeutic interventions in otological practice. Preselection procedures, hearing-aid fitting and servicing sessions account for a large proportion of the workload of audiological services rendered. Many

hospitals in the UK have a satisfactorily working direct referral hearing aid clinic (DRHAC) managed by a senior audiologist<sup>10 11</sup> In many regions of the UK community audiologists (first tier) and then hospital based audiologists (second tier) decide if an ENT specialist consultation is warranted (third tier) in cases with hearing loss The role of the community based paediatric audiological services in screening pre-school and school children with hearing impairments cannot be underestimated

Cost issues affect bilateral hearing aid fitting in most state-supported health schemes However, it is possible that the practice is perhaps determined and dictated by the knowledge and attitudes of the otolaryngologists and audiology teams of each region Nowadays, prescription of binaural hearing aids for children with bilateral otitis media with effusion is an acceptable option<sup>12</sup> Binaural hearing aid fitting has become more widespread in many parts of the world since coverage for two aids has been approved by the insurers<sup>13</sup> Attitudes and satisfaction studies have been undertaken amongst bilateral hearing aid users by several authors In a study by Stephens SDG et al, 55% of patients in the 50-65 years age group opted for binaural fitting and the choice was made for acoustic reasons, particularly on the basis of improved localisation ability<sup>2</sup> In another trial group most patients preferred binaural aids in quiet situations but monaural aids in noisy environments<sup>14</sup> A large subjective ratings study of aided hearing ability of binaural HA users compared with monaural HA users and normal hearing people clearly demonstrated the benefits of binaural amplification in many listening situations<sup>3</sup> One other NHS postal questionnaire survey among binaural HA users revealed enhanced auditory performance, social competence and personal enjoyment of life<sup>15</sup> In another study 90% of patients in a cohort of thirty bilaterally hearing impaired preferred binaural amplification and the authors concluded that routine practice of fitting monaural hearing aids may not provide optimum benefit<sup>16</sup>

There are no studies evaluating the knowledge, attitude and practice (KAP in Community Health terminology) of binaural aid prescription in the literature We undertook the task of evaluating this in an effort to understand the practice as it exists today in the UK, having recently celebrated 50 years of its successful state-administered National Health Service (NHS) The results of the study threw light on several issues including inadequate knowledge, indifferent attitudes and inconsistent practices as regards binaural aiding The majority of otolaryngologists of all grades identified financial constraints with bilateral fitting of aids Interestingly, the financial implication did not appear to be an influencing factor for the audiological physicians

With the exception of the audiological physicians, few practising otolaryngologists had prescribing guidelines or criteria However, a significant number (96, 17% of 561



respondents) of practitioners quoted 'children' under binaural fitting criteria. The Birmingham Otology Group uses the following guidelines for binaural fitting:

- a Bilaterally symmetrical deafness with thresholds (four tone average, 500 Hz, 1, 2 and 4 KHz) within 15 dB of each other
- b Children with bilateral deafness, both preschool and of school age take preference over adults for binaural fitting
- c Motivation and patients' professional needs are used as criteria with adults requiring binaural fitting

Bilateral BAHA fitting and bilateral cochlear implantation are still not acknowledged by most practitioners. 16 otolaryngologists expressed concern regarding future technological advances and the difficulties that may be encountered with bilateral cochlear implantees. Many of the retired consultants and some of the practising consultants who chose not to practise otology were reluctant to voice an opinion on some of the questions.

### **Conclusions**

The prescription of binaural hearing aids is poor both in the NHS and (to a lesser extent) in private practice.

Financial constraints and an apparent lack of prescribing guidelines appear to be the predominant reasons for the low rate of bilateral aid prescription.

Hearing aid prescription for unilateral hearing losses is practised in many parts of the country.

The attitude of many of the practising otolaryngologists towards bilateral BAHA and cochlear implants was indifferent.

An overwhelming majority of the practitioners believed that binaural hearing is as important as binocular vision.

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**Appendix 1:**
**Questionnaire**


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1. Please state your job title
  2. Are you aware of any studies in the literature that address the importance of binaural hearing?  
Yes/ No
  3. Do you prescribe bilateral hearing aids (air conduction) to patients in your practice?  
NHS Practice: Yes/ No                      If yes, what percentage?  
Private Practice: Yes/ No                      If yes, what percentage?
  4. Do you use criteria/ guidelines to prescribe bilateral hearing aids to a patient?  
  
Yes/ No  
If yes, can you quote any of them?
  5. Do you perceive financial constraints with the practice of bilateral hearing aids prescription?  
Yes/ No
  6. Would you prescribe a hearing aid for unilateral hearing loss?  
Conductive hearing loss:                      Yes/ No  
Sensorineural hearing loss:                      Yes/ No
  7. What is your attitude as regards bilateral bone anchored hearing aids (BAHA) prescription? (Tick one)  
a) I am aware of studies that show benefit                      (please quote)  
b) I do not believe there is sufficient evidence to demonstrate benefit  
c) I do not believe they work  
d) I have no opinion
  8. What is your attitude towards bilateral cochlear implantation? (Tick one)  
a) I am aware of studies that show benefit                      (please quote)  
b) I do not believe there is sufficient evidence to demonstrate benefit  
c) I do not believe they work  
d) I have no opinion
  9. Do you believe binaural hearing is as important to a person as binocular vision?  
  
Yes/ No
  10. Any other comments
-

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# **PART IV**

## **MODIFIED SURGICAL TECHNIQUE**



# Chapter 9

## **Modified incisions for reduction of soft-tissue for One-stage Bone Anchored Hearing Aid implantation**

How I do it / Otology and Neurotology / A specific Issue and its Solution

T Narayana Reddy, Sunil N Dutt, Kunal Gangopadhyay



## Introduction

The majority of patients who require a hearing aid can be fitted with an air-conduction hearing aid. If an air-conduction hearing aid cannot be used because of recurrent otorrhea or atresia of the auditory canal, it may be possible to fit a bone-conduction hearing aid. An alternative to the conventional bone-conductor aid is the Bone Anchored Hearing Aid (BAHA). BAHA has both cosmetic and acoustic advantages over any conventional aid and hence is a popular choice today.<sup>1</sup>

BAHA is coupled to a percutaneous titanium implant anchored in the temporal bone. The absence of interposing soft tissues (direct bone conduction) gives better quality sound, requires less energy and offers much greater comfort.<sup>2</sup> A thin layer of non-hair-bearing skin is required at the implant site.

Insertion of percutaneous implant into the temporal bone for the coupling of a BAHA can be done in two stages. The surgical steps can be divided into anesthesia and skin preparation, incision and soft tissue reduction, placement of fixtures, skin graft and abutment placement and dressings and aftercare.

## Technique

This brief report illustrates a modified incision to facilitate soft tissue reduction under direct visual control. An area of circular skin of 1.5 - 2 cm diameter is excised and subcutaneous tissue over an area of 1 cm around this is removed to allow the edges of the skin to drop down to the periosteum without any tension. Soft tissue reduction around this circular incision is facilitated by four radial incisions of 1-cm length extending from it (Figure 1).

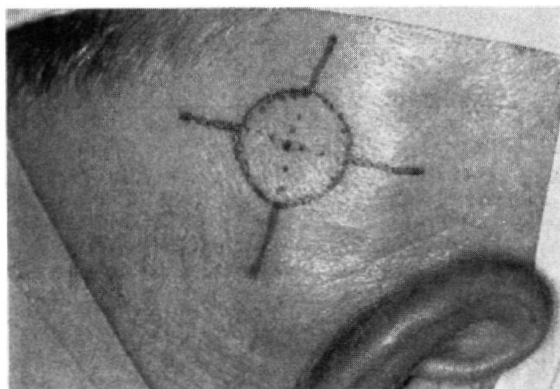


Fig. 1. Clinical appearance of the circular island for skin and soft tissue excision and the markings for the four-flap soft tissue reduction technique.





Fig. 2. Operative view showing elevation of the flaps to facilitate circumferential soft tissue reduction (doughnut shaped) under direct visual control.

Soft tissue reduction is done under direct visual control with a cutting diathermy and haemostasis is achieved by the use of a coagulation diathermy (Figure 2). The drilling procedure and insertion of the fixture and abutment are performed. A free skin graft is harvested from the postauricular skin, thinned and sutured over the fixture. The skin around the implant then makes direct contact with bone tissue. A punch is used to puncture the graft and the abutment is placed on the fixture, which penetrates through the skin graft. A healing cap is fitted over the abutment with half - inch ribbon gauze soaked in steroid-antibiotic ointment meticulously packed around between the healing cap and the skin graft. A pressure dressing is applied for at least 24 hours.

### Discussion

Reduction of soft tissue around a circumferential incision (back-cut and under-cut the free skin edge) on a vascular area like the scalp could be quite difficult unless carried out under direct visual control. The management of soft tissue around the implant site is important to achieve immobility of the skin around the penetrating abutment. This is vital for long-term care and maintenance of the fixture-abutment assembly by the patient.<sup>3</sup> If this is not undertaken adequately and accurately, the soft tissues including the temporalis and occipitalis muscles tend to sag and prolapse onto the abutment, with time.<sup>3</sup> We believe the described technique is a useful method of avoiding wound revision surgery at the implant site.

Over the last 5 years, the senior author (TNR) has used this modified incision to achieve soft tissue reduction under direct vision in 20 patients. Figure 3 shows the post-operative

appearance of the operated area in one of the patients. To date, we have not had any patient needing revision surgery for further soft tissue reduction at the implant site.



Fig. 3. Postoperative view showing satisfactory apposition of skin graft and circumferential flaps to underlying periosteum.

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# **PART V**

## **SUMMARY AND CONCLUSIONS**



# **Chapter 10**

## **Summary and conclusions**



In the last two decades otology has undergone a sea change. Firstly, there was the excitement of surgical innovation and the possibilities it presented. Surgical innovations have led to the emergence of a new era in otology known as 'Implantation Otology' that encompasses all types of partially implantable hearing devices that are used in hearing rehabilitation. However, the innovations were later tempered by the realisation that the results were less than hoped for like in the transcutaneous Xomed device. Of particular concern was the unpredictability of outcomes and the inconsistencies of outcome analysis and reporting between centres.

There followed a general understanding of the need for outcome measures with meaningful standardisation to allow comparison and permit attempts to predict whether intervention would be of benefit to the patient. This resulted in a more thoughtful approach to otological surgery exemplified by the "Belfast rule of thumb" and the "Glasgow Benefit Plot".

Now we have entered a third phase, which could be characterised as consumerist. This has two parts; the first is based on 'patient satisfaction scores' and 'patient report of benefit'. The second is an attempt to look at the 'cost-benefit analysis' of procedures in terms of improved quality of life (QUALY: Quality Adjusted Life Years).

In this dissertation, an attempt has been made to address the first of those two consumerist issues that is 'the patients perception of life benefit'. In 1996 the Birmingham Osseo-integrated Group published the results of the Bone Anchored Hearing Aid Programme from 1988 - 1995. In that supplement the team reported on surgical methods, the referral pattern, paediatric experience and the results in specific otological circumstances.

The anxieties about success rate in conventional otological surgery, especially that undertaken for hearing and the predictability of such surgery are still with us. The bone anchored hearing aid offers a low risk, highly acceptable method of aural rehabilitation for those with a conductive or mixed hearing loss and most importantly it is possible to predict the benefit for the patient with a high degree of accuracy.



Most of the papers are based on questionnaires addressed to the patients who have been the recipients of aural rehabilitation

#### *Chapters 2, 3 and 4*

Chapter 2 evaluated the use of a validated questionnaire, the Glasgow Benefit Inventory (GBI) in measuring patient satisfaction with the BAHA. A high degree of patient satisfaction with the BAHA was revealed. However, a low response rate from the paediatric group was noted. This finding has led to the generation of a generic paediatric satisfaction and quality of life questionnaire and the study is in progress.

Chapter 3 used the Nijmegen group questionnaire to compare the previous conventional aid with the bone anchored hearing aid. Here again, the BAHA received a significantly higher satisfaction score than the previous aid in the majority of patients on all counts. Day to day use and service related issues that were evaluated in chapter 4 using the Entific Medical Systems questionnaire revealed that the patients were satisfied with the service.

#### *Chapter 5*

This paper on the outcome domains of disability, handicap and benefit evaluation required a prospective interview with patients attending follow-up clinics in the adult BAHA programme. The use of the two instruments GHABP and the GHADP (Glasgow Hearing Aid Benefit and Difference Profiles, see appendix chapter 5) displayed very dramatically the hearing aid benefit with the BAHA and reduction in residual disability.

#### *Chapters 6 and 7*

The experience of the Birmingham BAHA programme with bilateral application of BAHA is modest. Chapter 6 evaluated subjectively the benefits of bilateral application of the BAHA with positive results in a small cohort of 11 patients. These findings were further supported

by semi-objective audiological measurements including the modified Plomp test discussed in chapter 7. Further analysis of these patients is underway including the 12-speaker sound localisation testing.

### *Chapter 8*

No studies were available in the literature on the knowledge, attitude and practice of hearing aid prescription amongst ENT surgeons. The Birmingham Otology Group set out to evaluate the same in the form of a simple cross-sectional survey study in the United Kingdom. The large majority was aware of the existing evidence of benefit of bilateral fitting but almost the same number limited prescriptions because of cost. The awareness of benefit of bilateral prescription of other devices such as cochlear implants was less good, which is reassuring as the study is not yet complete!

### *Chapter 9*

A simple four flap technique with complete visual control of the edges during soft tissue reduction is a technique useful in patients with excessive soft tissue at the implant site. This technique developed by one of the BAHA units (Stafford) in the West Midlands has been presented with a view to obviate the need for revision wound surgery and hence limit the number of wound and soft tissue complications.

No attempt has been made to perform a cost-benefit analysis as the costings need refinement. However, the dramatic reduction in the number of visits to the ENT department and general practice by those fitted with the bone anchored hearing aid will, over a lifetime of use, generate great savings in cost, time and suffering.

We hope that this series of papers will not only make a strong case for the benefit of the bone anchored hearing aid, but by using this consumerist method be the vanguard of this approach, which puts the patients' perceptions at the centre of the evaluation.



## ACKNOWLEDGEMENTS

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**CURRICULUM VITAE**

The author, Dr Sunil N Dutt, was born in Bangalore, India on the 16<sup>th</sup> of July, 1966. After completion of secondary education with honours and distinctions, he joined St John's Medical College and Hospital in Bangalore University in 1984. At the University Convocation in 1992, the Governor of Karnataka State conferred 12 gold medals to Dr Dutt for outstanding performance in MBBS. Dr Dutt proceeded to Bombay to pursue a residency in Otolaryngology and Head and Neck Surgery at the King Edward the VII Memorial Hospital. This culminated in procuring the qualifications of Diploma in Oto-Rhino-Laryngology (DORL), College of Physicians and Surgeons, Bombay, Master of Surgery in ENT (MS-ENT), Bombay University and Diplomate of the National Board of Examiners (DNB-ORL) between 1993 and 1994.

During his position as lecturer in St John's Medical College, Bangalore, Dr Dutt applied for further higher specialist training in the United Kingdom with sponsorships by Dr Mahadevaiah from Bangalore, Mr TN Reddy from Stafford and the Royal College of Surgeons of England, Overseas Doctors' Training Scheme (ODTS), London. Since 1995, Dr Dutt has been trained in various aspects of Otolaryngology in the West Midlands rotation in England following a Diploma in Laryngology and Otology, Royal College of Surgeons in England (DLO-RCS, Eng) and a Fellowship of the Royal College of Surgeons in Edinburgh (FRCS Ed). He pursued his special interests in Otology, Neurotology and Implantation Otology in Birmingham in the final three years of his training (1999 to 2001). During his training years Dr Dutt has published extensively and has presented papers related to his special areas of interest in academic meetings and international conferences. He has been awarded a number of prizes and travel fellowships. He passed the Intercollegiate Examinations in Otolaryngology in November 2001 in Dublin (FRCS - ORL HNS).

Dr Dutt's association with Nijmegen and Gothenburg came about with the Journal of Laryngology and Otology Travel Fellowship in 2001. This has culminated in the production of this thesis with the compilation of all his work on bone anchored hearing aids from the Birmingham BAHA Programme.

Dr Dutt is presently an Assistant Professor in Otolaryngology and Head and Neck Surgery, St John's National Academy of Health Sciences, Bangalore, India.

He is married to Dr Chandrika S Dutt, and has two children, Miss Aishwarya S Dutt and Master Aditya S Dutt.

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